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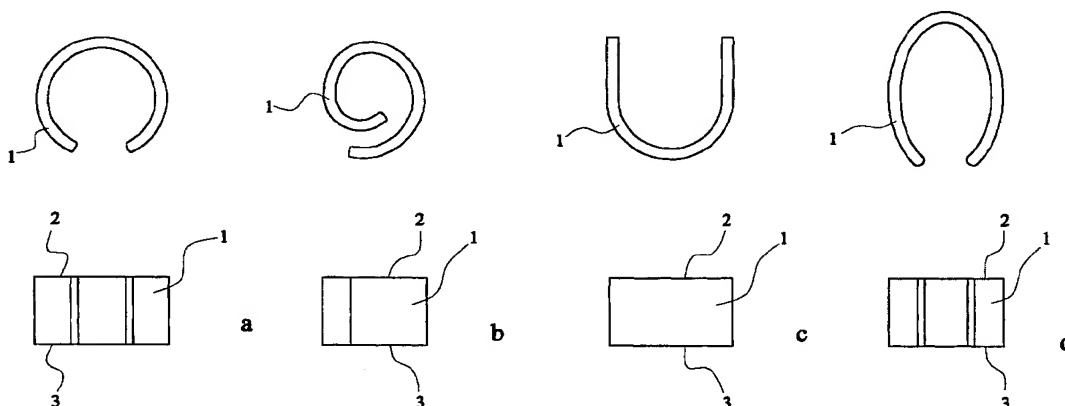
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(54) Title: **IMPROVED SPINAL FUSION IMPLANTS AND TOOL FOR INSERTION**



(57) Abstract: A vertebral-column device that is suitable to be received in an intervertebral space between two dorsal vertebrae, said prosthesis comprising a curved strip of biocompatible material and the width of said strip being such that after placement said strip makes contact with the aforementioned vertebrae, the strip being manufactured from a material that can undergo great deformations before permanent deformation arises, and the strip being curved in a shape in which the extremities are situated apart from one another and the radius of the curved parts and the thickness of the strip being chosen in such a way that when the strip is bent out into an approximately straight strip scarcely any permanent deformation arises, in which case the strip which has been bent out into an approximately straight strip is capable of being introduced into an intervertebral space where the strip assumes its original curved shape.



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## IMPROVED SPINAL FUSION IMPLANTS AND TOOL FOR INSERTION

The invention concerns improvements in and relating to vertebral-column fusion devices, surgical apparatus and surgical methods. In particular, but not exclusively, the invention relates to a vertebral-column fusion device that is suitable to be received in an intervertebral space between two dorsal vertebrae, said a fusion device comprising a curved strip of biocompatible material, with the width of the strip being such that after placement said strip makes contact with the aforementioned vertebrae.

Fusion devices aim to promote fusion of the adjoining vertebrae together. As such they are distinct from disc replacements where the new disc aims to mirror the behaviour of and given the mobility of the natural disc it replaces.

Fusion devices, in the most general sense, are known and are employed in cases where, as a result of accident, overloading, old age or otherwise, an intervertebral disc of the dorsal vertebral column is no longer able to perform its normal supporting and stabilising function. In these cases there is fitted in the space of said intervertebral disc a device which entirely or partially takes over the load-bearing function of the intervertebral disc until bone fusion has taken place. Known fusion devices of this type are constituted by a so-called cage construction with a closed peripheral surface which, for example, may have a cylindrical shape, and two end faces which after placement make contact with the two vertebrae bounding the intervening space. This type of fusion device is introduced into the intervertebral space by means of a surgical intervention and is manoeuvred into a precise position. Moreover, for good stability and satisfactory load-bearing capacity it is

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usually necessary to fit two of these device in the intervertebral space, side by side, one on each side of the vertebral column.

One disadvantage of these known devices is that they are difficult to fit in the intervertebral space, fitment being effected by means of a labourious, time-consuming and therefore expensive surgical intervention, in the course of which a relatively large access opening has to be made, with destabilisation and local trauma as a consequence. In the case of a posterior approach this is effected, as a rule, on the left and / or right sides of the spinal cord and in either case results in a fairly serious intervention.

The invention has amongst its aims to provide a better device that is simpler to fit in the intervertebral space and that, while preserving the simplicity of fitting, can nevertheless have a larger and therefore more favourable bearing surface than the known devices. The invention has amongst its aims to provide advantageous surgical apparatus for introducing devices into an intervertebral space. The present invention has amongst its aims to provide an advantageous surgical method for introducing a fusion device into an intervertebral space and / or for using surgical apparatus.

According to a first aspect of the invention we provide an intervertebral fusion device, the device comprising an elongate element, the elongate element providing one or more upper load bearing surfaces and one or more lower load bearing surfaces, the upper and lower load bearing surfaces being vertically spaced from one another by the elongate element, the elongate element having a first state and a second state, the elongate element having a substantially linear configuration in the first state and a less linear configuration in the second state, the elongate element



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being capable of transition, at least once, from the second state to first state and being capable of transition, at least once, from the first state to the second state, the elongate element being of shape memory alloy.

Preferably the intervertebral fusion device promotes fusion of one vertebrae to an adjacent vertebrae with the device there between. Fusion may be promoted by the ingrowth of bone or other material. The fusion device may restrain movement of one vertebrae relative to the other vertebrae the fusion device contacts.

The elongate element may be a substantially planar element, for instance a strip or sheet.

The elongate element may have a non-rectilinear cross-section at one or more locations along its length. The non-rectilinear cross-section may be provided throughout the length. The non-rectilinear cross-section may be provided at a plurality of locations along the length, with a rectilinear cross-section being provided at a location between two or more of those locations, ideally between each of those non-rectilinear cross-sections. The non-rectilinear cross-section may provide an increased thickness portion at the upper edge/upper load bearing surface and/or at the lower edge/lower load bearing surface of the elongate element. The non-rectilinear cross-section may be of a linear C-shaped cross-section. The portions of the elongate element having a non-rectilinear cross-section may have the same profile in the first and second states. The portions of the elongate element between the non-rectilinear portions may flex and/or bend during the change from first to second state and/or vice-versa.

The elongate element may be a mesh. The elongate element may be continuous or may have one or more holes or

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apertures in it. The holes may be round and / or oval and/or triangular and/or diamond shaped.

The elongate element may have a linear upper load bearing surface or surfaces. The elongate element may have a discontinuous upper surface. One or more indentations may be provided in the upper load bearing surface. The elongate element may have a serrated upper load bearing surface or surfaces. The elongate element may have one or more protrusions or spikes provided on the upper load bearing surface or surfaces. The upper surface of the elongate element may be defined by one or more, preferably linear, load bearing surfaces interspaced by one or more indentations. The indentations may be triangular in shape. The upper load bearing surface or surfaces of the elongate element may be provided with one or more protrusions or teeth. The protrusions or teeth may have a triangular profile.

The elongate element may have a linear lower load bearing surface or surfaces. The elongate element may have a discontinuous lower surface. One or more indentations may be provided in the lower load bearing surface. The elongate element may have a serrated lower load bearing surface or surfaces. The elongate element may have one or more protrusions or spikes provided on the lower load bearing surface or surfaces. The lower surface of the elongate element may be defined by one or more, preferably linear, load bearing surfaces interspaced by one or more indentations. The indentations may be triangular in shape. The lower load bearing surface or surfaces of the elongate element may be provided with one or more protrusions or teeth. The protrusions or teeth may have a triangular profile.

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The upper and lower load bearing surface and/or one or more of the upper and lower load bearing surfaces may be parallel to one another. The upper and lower load bearing surface and/or one or more of the upper and lower load bearing surfaces may be angled relative to one another. The angle between a projection of the upper load bearing surfaces and/or at least one of the upper load bearing surfaces and the lower load bearing surface and/or at least one of the lower load bearing surfaces may be  $5^{\circ}$  to  $15^{\circ}$ , more preferably  $7^{\circ}$  to  $13^{\circ}$ . More preferably the angle is  $8^{\circ}$  to  $12^{\circ}$ , still more preferably  $9^{\circ}$  to  $11^{\circ}$  and ideally is  $10^{\circ}$ . One or both of the upper or lower load bearing surfaces may be non-perpendicular to the height of the elongate element.

The upper and/or lower load bearing surface or surfaces may contact and/or enter the vertebrae in use.

The vertical spacing of the upper and lower load bearing surface or surfaces may be between 7mm and 20mm, preferably between 8mm and 17mm and ideally between 9mm and 15mm. The maximum vertical spacing is preferably less than 22mm, more preferably less than 19mm and ideally less than 17mm. The maximum vertical spacing is preferably provided at one or both ends of the elongate element, particularly when the device is introduced from the anterior side of the patient. The maximum vertical spacing is preferably provided within the middle portion of the elongate element, particularly when the device is introduced from the posterior side of the patient.

The minimum vertical spacing is preferably more than 4mm, more preferably more than 5mm and ideally more than 6mm. The minimum vertical spacing is preferably provided at one or both ends of the elongate element, particularly when the device is introduced from the posterior side of the patient. The minimum vertical spacing is preferably

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provided within the middle portion of the elongate element, particularly when the device is introduced from the anterior side of the patient.

The first state may provide a linear configuration for the elongate element. The first state may provide a non-linear configuration, for instance a curve or waveform, for the elongate element. A non-linear configuration may mean one end of the elongate element being offset from a tangent to the other end by less than 5mm, preferably less than 4mm, more preferably less than 2mm and ideally less than 1mm. A non-linear configuration may mean one or more portions of the elongate element being disposed to one side or the other side, relative to a centre line of the elongate element. The one or more portions may be so disposed by one or curves, preferably alternating direction curves, ideally a waveform. The first state may provide a configuration in which one end of the elongate element is further, in a straight line, from the other end of the elongate element than any other component. The part of the elongate element intervening the two ends may be non-linear, for instance including one or more curves. A wave form consisting of alternating curves of opposing direction is particularly preferred.

The second state may provide a configuration in which at least a part of the elongate element is curved. The second state may provide a situation in which the entire length of the elongate element is curved. The curve may be of constant radius throughout the length of the elongate element. The curve may be a various radii over the length of the elongate element. The minimum radius is preferably at least 3mm and more preferably 5mm.

The second state may provide a configuration in which at least a part of the elongate element is curved and in

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which at least a part of the elongate element has a waveform and/or serpentine and/or wavy profile. The parts may be the same part of the elongate element. The curves forming the waveform may have a radius of less than 1mm.

In the second state the elongate element may have a configuration which is a part circle and/or full circle and/or spiral and/or U-shape and/or a part oval and/or full oval. The ends of the elongate element may be touching or may be apart in the second state. One end of the elongate element may be tucked behind the other in the second state, touching or not touching

Preferably the elongate element is formed of a single piece of shape memory alloy.

The shape memory alloy is preferably an alloy of titanium, most preferably with nickel. The shape memory alloy may be an alloy of copper and zinc and/or aluminium. The shape memory alloy may be an alloy of iron and nickel. The shape memory alloy may be an alloy of copper, aluminium and nickel. The alloys may include other elements.

The transition from second state to first state is preferably provided in the warm state for the shape memory alloy. The transition from the first to second state is preferably provided in the warm state for the shape memory alloy. The elongate element may be brought into in the cold state, prior to or during insertion and/or be in the cold state after insertion, at least temporarily. The transition from first state to second state may be caused by the elongate element passing from the cold state to the warm state in the patient. The passage from cold state to warm state may be caused by body heat and / or external heating.

The transition from second to first state is preferably achieved by the application of stress to the elongate

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element. The transition from first to second state is preferably achieved by the removal of the application of stress to the elongate element.

The shape memory alloy preferably undergoes pseudo-plastic deformation during the transition from first to second state. The transition from first to second state preferably involves a strain of less than 10% for any part of the elongate element, more preferably the elongation is less than 8% for any part.

The elongate element preferably has a thickness, for instance perpendicular to the vertical in use, of less than 2mm and more preferably of less than 1.5mm. A thickness of between 1mm and 1.5mm is preferred.

The elongate element may have a constant thickness throughout its length and/or width. The elongate element may be provided with one or more reduced thickness portions. The reduced thickness portion or portions may be provided by recesses and/or notches and/or grooves in the elongate element. Preferably the surfaces defining the elongate element and feature defining the reduced thickness portion are connected by rounded surfaces. The reduced thickness portion may have an extent along the elongate element at that reduced thickness. The feature defining the reduced thickness portion may include a curved portion linking the elongate element at normal thickness to the elongate element at reduced thickness, with a further curve linking the reduced thickness to the normal thickness of the elongate element. Preferably the feature defining the reduced thickness portion is provided on the outside surface of the elongate element. The feature defining the reduced thickness portion preferably extends throughout the width of the elongate element. The features defining the reduced thickness portion may be regularly spaced along the length

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of the elongate element. The features defining the reduced thickness portion or portions may be irregularly spaced along the length of the elongate element. In particular, the features defining the reduced thickness portion may be preferentially provided in the portion of the elongate element which undergoes the greatest change, even the change, in profile between the first and second state. The features defining the reduced thickness portion may be less frequently provided or absent from the portion or portions of the elongate element undergoing least or no change in profile between the first and second state.

Where the elongate element includes one or more reduced thickness portions and / or one or more enhanced thickness portions, it is preferred that the elongate element have a minimum thickness, in the reduced thickness portions, of at least 0.4mm. It is preferred that the elongate element has a maximum thickness, in the non-reduced thickness portions, or enhanced thickness portions of at most 3mm.

The maximum extent of the elongate element, measured from any point to any other in a straight line, is preferably less than 50mm, more preferably less than 40mm and ideally less than 35mm. The maximum extent of the elongate element, measured from any point to any other in a straight line, is preferably at least 7mm, more preferably at least 10mm and ideally at least 12mm.

One or both ends, preferably only the trailing end during insertion, of the device may be provided with an engagement profile. the engagement profile is preferably used to link the device to a surgical instrument, particularly a surgical instrument for inserting the device. the engagement profile preferably provides an engagement with the instrument during insertion and / or removal and /

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or manipulation and / or advancement and / or retraction of the device.

The engagement profile preferably provides one or more surfaces, at least in part, facing away from the other end of the device. Such a surface may provide an abutment surface during insertion. The engagement profile preferably provides one or more surfaces, at least in part, facing the other end of the device. Such a surface may provide an abutment surface during retraction and / or manipulation.

The engagement profile may include a surface extending from the end of the device, a second surface extruding from the end of the device and a third surface linking the two. The third surface may be generally parallel to the end of the device. The first and second surfaces are preferably non-perpendicular to the end of the device and / or non-parallel to one another. The engagement profile may define a protruding dovetail from the end of the device, ideally defined by the first, second and third surfaces.

The engagement profile may include a recess in the device defined by a first surface extending into the device, a second surface extending into the device and a third surface linking the two. The third surface may be generally parallel to the end of the device. The first and second surfaces are preferably non-perpendicular to the end of the device and / or non-parallel to one another. The engagement profile may define a recessed dovetail, ideally defined by the first, second and third surfaces.

The invention may be a vertebral-column device / prosthesis, suitable to be received in an intervertebral space between two dorsal vertebrae, said prosthesis comprising a curved strip of biocompatible material and the width of said strip being such that after placement said strip makes contact with the aforementioned vertebrae,



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characterised in that the strip is manufactured from a material that can undergo great elastic deformations before permanent deformation arises, and the strip is curved in a shape in which the extremities are situated apart from one another and the radius of the bent parts and the thickness of the strip are chosen in such a way that when the strip is bent out into an approximately straight strip scarcely any permanent deformation arises, whereby the strip which has been bent out into an approximately straight strip is capable of being introduced into an intervertebral space where the strip assumes its original curved shape.

The strip may be manufactured from a shape memory alloy / memory material, such as an alloy of titanium and nickel, which can undergo great deformation before permanent deformation arises.

The curved strip may have a U-shape. The curved strip may have a circular shape. The curved strip may have a spiral shape. The strip may have an oval shape.

The strip may have a thickness of 1.5 mm and the curved parts of the strip exhibit a radius of at least 12.5 mm. Where the minimum thickness of the elongate element is less than 1.5mm, for instance, less than 1mm, the curved parts of the strip may exhibit a radius of at least 8mm.

The strip may be provided with holes. The strip may have a gauze structure.

The strip may have provided on its sides with projections which after the strip has been fitted in the intervertebral space come into contact with the two vertebrae bounding said space and fix the strip with respect to them.

According to the invention the device exhibits the characteristic that the strip is manufactured from a material that can undergo great deformations before

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permanent deformation arises, and the strip is curved in a shape in which the extremities are situated apart from one another and the radius of the curved parts as well as the thickness of the strip are chosen in such a way that when the strip is bent out into an at least approximately straight strip scarcely any permanent deformation arises, in which case the strip which has been bent out into an approximately straight strip is capable of being introduced into an intervertebral space where the strip assumes its original curved shape.

The material of the strip may, moreover, be constituted by a shape memory alloy / memory material such as an alloy of titanium and nickel. Such a material has, besides its advantageous property that it delivers virtually constant force in the course of progressive deformation, the additional property that it can undergo very great deformations of up to 6 % to 8 % without the material deforming permanently.

In the case of the devices according to the invention, optimal use is made of the aforementioned properties by giving the strip such a curved shape that crosscut edges are obtained which form a bearing surface of the desired dimension for the vertebrae. Moreover, the curves of the strip are given a radius such that, given the thickness of the strip which arises when the strip is bent out into a straight strip, scarcely any or no permanent deformations arise - that is to say, the deformations remain below the order of 6 % to 8 % straight can easily be inserted via a narrow slit-shaped incision into the intervertebral space where the strip then reassumes its original curved shape. Because the curved strip can have crosscut faces of substantial dimension in comparison with the crosscut faces of known devices, with the device according to the invention

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it is possible to use only one device which provides satisfactory load-bearing strength and stability in an intervertebral space. In this way the fitting of the device becomes simpler, because only one small opening is necessary for the insertion, causing less trauma. Depending on circumstances, the strip according to the invention can be curved in a U-shape, a circular shape, a spiral shape, a rectangular shape or any other desired shape. Another favourable design of the device according to the invention exhibits the characteristic that the strip has a thickness of 1.5 mm and the curved parts exhibit a radius of at least 12.5 mm. In this way it is ensured that when the strip is bent out into an almost straight strip the deformation of the strip in the curved parts remains below 8 %, so that no permanent deformation or scarcely any permanent deformation arises and the strip reassumes its original curved shape after its introduction into the intervertebral space.

In order to promote a successful ingrowth and accretion of bone, according to a further embodiment of the devices according to the invention the strip is provided with holes or the strip is designed in the form of a gauze.

In order to fix the device well in its place after fitment in the intervertebral space, according to a further embodiment the strip is provided on its sides with projections which come into contact with vertebrae bounding the space and consequently oppose a displacement with respect to them.

According to a third aspect of the invention we provide a method of surgery, the method including the acts of :-

making an incision in the patient;

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removing at least part of an intervertebral disc from the patient through the incision, thereby providing an intervertebral disc space; and

inserting a device into the intervertebral space;

the device comprising an elongate element, the elongate element providing one or more upper load bearing surfaces for a vertebrae and one or more lower load bearing surfaces for a vertebrae, the upper and lower load bearing surfaces being vertically spaced from one another by the elongate element, the elongate element having a first state prior to insertion and a second state after insertion, the elongate element having a substantially linear configuration in the first state and a less linear configuration in the second state, the elongate element undergoing transition, from the first state to the second state within the patient, the elongate element being of shape memory alloy.

The device may have any of the features, options or possibilities set out elsewhere in this document, including the first and / or second and / or sixth aspects of the invention.

The incision may be made anteriorally and/or posteriorally. Preferably the incision is less than 5cm long, more preferably less than 3cm long.

Preferably at least the nucleus pulposus is removed. The annulus fibrosus and/or vertebral end-plate may also be removed.

The device may be inserted using surgical apparatus. The surgical apparatus may be provided as detailed in the fourth and/or fifth aspects of the invention and/or as described elsewhere in this document.

Whilst only a single device may be inserted in the intervertebral space between any two vertebrae, a plurality of devices may be inserted. Two or more devices may be

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inserted into a position where they are alongside one another. Two or more devices may be inserted into a position where at least a part of one of the devices is enclosed by one of the other device's and/or lies within the outline of one of the other device's. Two or more devices may be inserted such that an opening defined between the two ends of one of the device's is opposed by at least a part of another device. Bone graft material may be provided within the outline of one or more of the devices. Bone graft material may be provided between at least a portion of one device and at least a portion of another device.

In the method the end of the apparatus, particularly the end of the holding frame, may be inserted into the incision and ideally between the vertebrae. The apparatus is preferably inserted in one orientation and rotated to a second orientation after insertion. The second orientation may be between 70 and 110° of the first. Preferably the end of the apparatus abuts the opposing vertebrae during rotation. Preferably continued rotation increase the separation of the opposing vertebrae. In this way easier access to the vertebral space may be gained.

The insertion of the device may cause the transition from first to second state, particularly where the restraining force is removed by insertion. The transition from first to second state may occur after insertion of the device, particularly where the transition is caused by the device passing from cold state to warm state. The passage of the device from cold to warm state is preferably at least in part be caused by warming due to the patient's body heat. Additional heating for the device may be provided, particularly external heating. The temperature of the device may be raised to at least 40°C and ideally to between 40°C and 50°C by external heating.

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The method may include the ingrowth of bone or other material to complete the fusion after insertion.

The method may include retraction of the device. The method may include manipulation of the device. Preferably manipulation and / or retraction and / or insertion are provided using surgical apparatus according to the fourth or fifth aspects of the invention and / or by means of a profile on the end of the device as provided in the second aspect of the invention.

The method may include retraction of the device into the apparatus. The method may include retraction of the device so as to cause the device to change from the second state into the first state. The method may include the retraction of the device into the surgical apparatus.

The present invention also relates to apparatus that is suitable for the insertion of a device as described above into an intervertebral space.

According to a fourth aspect of the invention we provide surgical apparatus for inserting a device into a patient, the apparatus including a holding frame for the device, a pushing element configured to enter the holding frame, at least one hand operated component, the hand operated component being indirectly or directly linked to the pushing element, operation of the hand operated component advancing the pushing element into the holding frame.

The device may be as described in the first and/or second aspect of the invention.

The holding frame preferably extends along an axis. The cross-section of the holding frame perpendicular to the axis is preferably constant. Preferably the holding frame has an axial extent greater than the device, particularly relative to the first state for the device mentioned above.

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The holding frame is preferably continuous. The holding frame may be tubular. The tubular form may have a circular cross-section, but preferably has a rectilinear cross-section. The rectilinear cross-section may be between 1 and 20% greater than the cross-section of the elongate element in the height direction. The rectilinear cross-section may be between 1 and 10% greater than the cross-section of the elongate element forming the device in the thickness direction. The holding frame may be between 1 and 25% longer than the device in the length direction.

The length direction for the device may be its elongate direction and/or longest dimension. The thickness direction for the device may be perpendicular to its elongate direction and/or its smallest dimension. The height direction for the device may be perpendicular to its elongate direction and/or its intermediate dimension of the three.

The holding frame may be sealed at one or both ends. Preferably the holding frame is sealed. The holding frame may be sealed by seals, preferably the pushing element breaks the seal when advanced in to the holding frame. Preferably the device breaks the seal when advanced out of the holding frame.

The holding frame is preferably detachable from the apparatus. The detachable holding frame may be fully sealed prior to use. Preferably the interior of such a holding frame is sterile prior to use. The detachable holding frame may be disposable or reusable.

The apparatus may have a body. The body may provide a mount for the holding frame and/or at least one hand operated component and/or pushing element.

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The pushing element may have a cross-section substantially corresponding to the cross-section of the device and/or the holding frame.

The pushing element may be mounted on a rod, shaft or other elongate element, particularly one end thereof.

The pushing element may advance the device by abutting the device and / or by engaging the device.

The pushing element may be retractable. Preferably the pushing element engages the device and facilitates retraction thereof. The engagement for the device may be provided by a profile in the pushing element. The profile may be a recess, slot or aperture. Preferably the profile cooperates with a portion of corresponding profile on the device. Preferably the profile provides one or more abutments between the pushing element and the device during advancement and / or retraction and / or manipulation. The profile may correspond and / or cooperate with a device profile as defined in the second aspect of the invention.

The at least one hand operated component may be pivotally mounted on the apparatus body and/or on a protrusion therefrom. The protrusion may be hand held in use. The at least one hand operated component preferably abuts on a driving element when operated. The at least one hand operated component preferably advances the driving element towards the holding frame when operated. The driving element preferably advances the pushing element and/or a mounting therefore towards the holding frame when operated. The driving element may have an aperture through which the mounting for the pushing element passes. The driving element preferably catches on the mounting when advanced towards the holding frame. The driving element may be biased away from the holding frame, for instance by a spring within the body. Preferably the driving element



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passes over the mounting when driven back away from the holding frame. The body may provide a restraining element. Preferably the restraining element resists movement of the pushing element and/or mounting therefore away from the holding frame. Preferably the restraining element is biased, ideally by a spring, away from the holding frame. The restraining element may be attached to the spring. Preferably the restraining element allows free movement of the pushing element or mounting therefore towards the holding frame.

According to a fifth aspect of the invention we provide apparatus suitable for introduction of the prosthesis according to one or more of the preceding claims into an intervertebral space, characterised in that the apparatus comprises an elongated tubular body with a receiving space for a strip which has been bent out in elongated manner, said apparatus being further provided with means for exerting a force on said strip for pressing the strip out of the receiving space into an intervertebral space.

The apparatus may have receiving space has a rectangular shape in cross-section.

The apparatus may have the means for exerting a pressing-out force on said strip are constituted by a rod, one end of which is provided with a part which enters into contact with the strip, said rod being guided within a wall bounding the receiving space, said rod being displaceable in stepwise manner in the direction of the receiving space by means appropriate for this purpose and being arrested in the other direction by a blocking mechanism which is capable of being cleared after the strip has been introduced, after which the rod can be removed from the receiving space. In the invention said apparatus may comprise an elongated

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tubular body with a receiving space for a strip which has been bent out in elongated manner, said apparatus being further provided with means for exerting a force on said strip for pressing the strip out of the receiving space into an intervertebral space.

Moreover, according to a preferred embodiment the cross-section of the receiving space is rectangular and the means for pressing the strip out are designed in such a way that pressing-out proceeds in stepwise manner.

According to a sixth aspect of the invention we provide an intervertebral fusion device, the device comprising an elongate element, the elongate element providing one or more upper load bearing surfaces and one or more lower load bearing surfaces, the upper and lower load bearing surfaces being vertically spaced from one another by the elongate element, the elongate element having a first state and a second state, the elongate element having a substantially linear configuration in the first state and a less linear configuration in the second state, the elongate element being capable of transition, at least once, from the second state to first state and being capable of transition, at least once, from the first state to the second state, the elongate element being formed of a plurality of elongate components which at least in part extend alongside one another.

The elongate element may be provided with a plurality of elongate components which contact one another over at least a part, preferably all, of their length. The elongate components may correspond to one another in form. The elongate components may be of matching form. The elongate components may be equivalent to one another. Three, four or five elongate components may be provided. The elongate

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components may be in the form of a plurality of equivalently configured strips, adjacent strips being in contact with one another.

The elongate components are preferably connected together to form a single elongate element. The elongate components are preferably connected together at one end, particularly the end which is inserted first into the patient. The elongate components may be connected together by one or more fastenings. The elongate components may be joined together by one or more adhesive components.

This aspect of the invention may include for its device any of the features, options or possibilities set out elsewhere in this document.

The invention will now be described by way of example only, and with reference to the accompanying drawings, in which:-

Figs. 1 a, b, c, d, e, f and g each show schematically, in two mutually perpendicular views, a shape of a device according to various embodiments of the invention;

Fig. 2 shows, schematically and not to scale, an example of a vertebral column with a device according to the invention received therein;

Fig. 3 shows schematically a further embodiment of the invention and comprising a bent-straight strip of a material, preferably

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memory material, which can undergo great deformations before permanent deformation arises;

Fig. 4 shows in cross-section, schematically and not to scale, one embodiment of an apparatus for inserting a device according to the invention into an intervertebral space;

Fig. 5 shows a cross-section of the apparatus end according to Figure 4 along line V-V;

Figures 6a and b illustrate two further embodiments of devices according to the invention;

Figure 7 illustrates an alternative embodiment of apparatus for inserting a device according to the invention into an intervertebral space;

Figure 8 illustrates the elongation with stress behaviour of memory metals during deformation and relaxing;

Figure 9a shows a partial view of two vertebrae and the end of an apparatus for dispensing a device according to the invention in the position in which it is initially inserted;

Figure 9b shows the partial view of Figure 9a with the apparatus rotated to the position in which the device is dispensed;

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Figure 10 shows schematically an alternative device according to an alternative form of the present invention;

Figures 11a, 11b and 11c show three different situations in which a pair of devices according to the invention are inserted between a pair of vertebrae; and

Figure 12 illustrates a detail of one end of a device according to yet another embodiment of the present invention.

In Figure 1a a device according to the invention is shown in the form of a strip 1 of shape memory alloy, commonly known as memory material or metal, which exhibits a circular shape.

In Figure 1b a device is shown consisting of a strip 1 of memory material which has a spiral shape.

In Figure 1c a device is shown which comprises a strip 1 of memory material which has a U-shape.

In Figure 1d a device is shown with a strip 1 of memory material which has the shape of an oval.

In Figure 1e a device is shown with a strip 1 of memory material which has an overall partial circular form, but in which the strip is also provided with a waveform along its length. The strip thus extends beyond and within, alternately, the dotted line circular profile. One of the key features for such a form of the device is that the thickness of the material at any point is not increased (thus maintaining flexibility) whilst the overall length of material inserted in a given location is increased. This in turn increases the surface area of the top and bottoms of

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the strip which are available to support the vertebrae in use. Equivalent bearing surfaces can effectively be provided, using such a profile, to a device as illustrated in Figure 1a, for instance, but with a thinner strip of material being used. The waveform also provides enhanced flexibility. Good flexibility for the device to ease insertion and good support capability for the device once positioned are thus both ensured. Such device forms may also be beneficial in the stored state, prior to use, where lower constraining forces may be needed to keep the device in the form ready for dispensing; in this case a waveform extending linearly as shown in the bottom of the three views of Figure 1e.

In Figure 1f again a device is shown in the form of a strip 1 of memory material which has a circular form. In this case the strip has a series of notches 1a in its external surface. The notches 1a have a maximum depth, into the thickness of the strip, of around 50% the thickness of the strip. The notches 1a extend across the full width of the strip in substantially the same profile and are evenly spaced along the length of the strip. The notches 1a in such a device provide locations to preferentially accommodate the deformation of the strip in the pre-dispense form. The remainder of the strip provides a significant thickness, and hence top and bottom surface areas, to achieve the desired level of support for the vertebrae they contact in use. Again a successful balance of flexibility to allow insertion and support area to maintain the separation of vertebrae is provided. The bottom illustration of the three in Figure 1f shows the device in its linear profile, suitable for dispense.

In Figure 1g another strip 1 is illustrated, on this occasion with a non-rectilinear cross-section in certain

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parts 1c. In these parts 1c the top and bottom load bearing surfaces of the strip 1 are extended. Between the expanded parts are rectilinear cross-sectioned parts 1d. It is at these parts 1d that most of the bending occurs during the transition from the first to second state and vice-versa. This linear C-shaped cross-section offers expanded support capability through increased bearing area, but still maintains flexibility.

The strip 1 of the foregoing figures is manufactured from a shape memory alloy which is constituted by an alloy of copper and zinc or titanium and nickel or nickel and iron. Shape memory alloys, due to their pseudo-plastic behaviour, has the property that it can undergo deformations of up to 8 % before it exhibits permanent deformations. By giving a strip of this material a thickness and radii of curvature so that in the course of its being bent out into a straight strip no deformations of more than 8 % arise, such a strip will reassume its original curved shape after being bent out into a straight strip and subsequently released. In practice, therefore, the devices according to Figures 1 a, b, c, d, e, f and g can be manufactured from a strip with a thickness of ideally 1.5 mm and the radii of curvature of the curved parts are ideally greater than 12.5 mm where a uniform thickness of strip is used. In the cases where reduced thickness portions are provided for the strips, the thickness could be considerably thinner, for instance down to 0.4mm, at those reduced thickness locations. The radius of curvature may also be less in such cases, for instance greater than 8mm. In this way, these strips will always resume their original shape after being deformed. This means that, after being deformed into an almost straight strip, such devices can be introduced, via a narrow slit made in the spine bounding the intervertebral space, into

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said intervertebral space where they then resume their original shape. In that position the end faces 2 and 3 then come into contact with the adjacent vertebrae, in which case the strip then performs a supporting and stabilising function for these vertebrae and thus takes over the load-bearing function of the intervertebral disc until bone fusion has come about. By virtue of the fact that the overall transverse dimension of this type of device can be fairly large, it is possible for the fitting of only one prosthesis to suffice.

An example of a device of the type according to the invention which is fitted in the intervertebral space of a vertebral column is shown schematically in Figure 2.

A strip 1 in the deformed state, is shown in Figure 3, wherein it is further indicated that such a strip may possibly also be provided with edges 4 and 5 which are not smooth but serrated. These serrated edges ensures that after placement of the device the latter remains well - positioned with respect to the vertebrae making contact with it. The strip may possibly also be provided with holes 6 which promote the ingrowth and accretion of bone.

For introduction of the strip 1, use may be made of apparatus according to Figure 4. Said apparatus comprises a tubular part 7 which, as shown in Figure 5, has a rectangular cross-section in which a strip 1, which has been deformed straight, can be received. On the end of the strip there rests a pressing-out block 8 which is provided on a long rod 9. Fastened to the rod 9, with some clearance, is a plate 10, whereby a spring 11 which presses said plate against one end of a rotatable operating lever 12 acts on one side of said plate. On the other side of the lever a spring 13 which presses a blocking lever 14 into its blocking state is fitted in the apparatus.



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The operation of the apparatus is as follows. By pressing the plate 10 to the right with the lever 12 said plate will tilt and thereby be locked onto the rod 9, which is moved to the right by further movement of the lever 12, as a result of which the block 8 will press the strip 1 outwards. By now moving the lever back to the left, the plate 10 will also move back with it. Moreover, the rod 9 remains in its place by virtue of the fact that movement thereof to the left is blocked by the blocking lever 14. In this way, by moving the lever 12 back and forth a number of times, the strip 1 will be pressed in stepwise manner out of the receiving tube 7 into an intervertebral space, for example. After the strip has been pressed out of the tube, the block 8 and the rod 9 can be brought back into their initial position by pressing on the blocking lever, as a result of which the blockage is cleared and the rod with the block 8 can be moved to the left.

Further potential embodiments for the device are illustrated in Figures 6a and 6b. In Figure 6a a strip 20 of material is provided with apertures 22 in the solid wall of the strip and indentations 24 in the upper and lower surface of the strip. The indentations 24 leave an upper load bearing surface 26 and lower load bearing surface 28 which due to their reduced surface area offers resistance to movement of the strip relative to the vertebrae. In the Figure 6a embodiment the strip is of greater height on one side of the curve (side A in Figure 6a) compared with the other side of the curve (side B in Figure 6a). In effect side B is the location on the strip where the opening between the two ends is provided. The different heights for the strip at different locations and a gradual tapering between the two on both upper and lower load bearing surfaces provides a closer match between the device and the

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attitude of the vertebrae in practice. The angle,  $\alpha$ , defined by a projection of the upper and lower surfaces, may be between 8 and 12° and is preferably 10°.

A similar embodiment of the device is illustrated in Figure 6b, but in this case the upper and lower load bearing surfaces are parallel to one another.

It is highly desirable that the device is formed of a single layer of material as this avoids the risk of delamination, relative movement or other issues which arise with multi layer materials. Strips of between 1 and 1.5mm in thickness can be used to provide sufficiently resilient devices which are capable of being straightened to a linear profile. A radius of approximately 15mm is preferred to effect a suitable fusion device using a single device.

It is preferred that the device is relatively flexible to forces exerted in the plane of the intervertebral space / intervertebral disc. It is preferred, however, that the height of the device and / or the height of the separation between vertebrae it maintains does not vary.

In the alternative embodiment of the apparatus illustrated in Figure 7, the permanent barrel of the Figure 4 embodiment is replaced by a disposable tube 30 which can be releasably fastened on to the end of the apparatus 32 by screw threaded portions 33. The device 34 is provided within the tube 30 and is sealed at both ends by barriers 36. The device 34, therefore, is provided to the apparatus in a fully sealed manner which maintains it sterile during transport and dispensing.

In use, in a similar manner to the description above for the Figure 4 embodiment, the piston 38 is advanced in the apparatus and pushes through the barrier 36 to contact the end 40 of the device 34 as a result. Continued advancement of the piston 38 pushes the device 34 forward

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and causes it to rupture the barrier 36 and thereafter pass into the intervertebral space.

The use of shape memory alloys, including memory metals, is advantageous during the dispensing process. Whilst the walls of the tube containing the device are used to restrain it during dispensing, once clear of the end of the tube the device begins to resume its original profile. The pseudo-elastic properties of memory metal materials, as illustrated in Figure 8, mean that there is a "delay" in the shape memory alloy resuming its configuration as the stress is removed. Because of this, shape memory alloys are far easier to dispense using such apparatus than other materials which would immediately return to their original configuration upon removal of the stress. The applicability of the invention is not dependant on this possibility.

To insert devices according to the present invention, a small incision is made and the disc in the intervertebral space for which fusion is to be effected is removed. The size of the incision is minimised to minimise surgical trauma. Subsequent to the disc's removal the end of the apparatus for dispensing the device is inserted into the aperture through which the disc has been removed. The end of the device is inserted with the device in a substantially flat orientation, see Figure 9a and is slowly rotated about its length to the orientation of Figure 9b. In this way the external surface 50 of the apparatus abuts the vertebrae as the apparatus is rotated, with continued rotation increasing the separation of the vertebrae to the desired level where the device can be introduced easily. The separation of the vertebrae may be assisted by the use of spreader blocks.

In addition to the above mentioned technique in which the device is straightened and then restrained during insertion to maintain it in the linear profile, it is

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possible to make use of the different properties of shape memory alloys in their respective cold state and warm state. In the warm state it is possible to straighten and physically restrain in a position a normally curved strip. If the temperature of the strip is then reduced, the deformation can be fixed using the cold state for the shape memory alloy. In this cold state the device can then be introduced into the intervertebral disc space, with the warmth of the body into which the device is inserted causing the device to warm up once more and pass from the cold state to warm state, whereupon the device assumes its original curved configuration. The warming process can be assisted beneficially by external heating of the device. The device may be heated up to between 40°C and 50°C and then allowed to cool. The hysteresis curve for the memory metal gives benefits in such a case.

Whilst the invention is particularly concerned with the use of shape memory alloys to achieve the desired balance of flexibility and support in a spinal fusion device, some of the benefits of the invention can be obtained through the use of carefully configured conventional materials, i.e. elastic materials. To achieve the aim of inserting the device through a small insert in the spine the device, Figure 10, is once again provided in the form of a strip 100 which assumes a U-shaped profile in use. To achieve the desired level of support in use from such materials a significant upper and lower surface area needs to be provided. With conventional material, however, this results in a strip which is insufficiently flexible to be placed in a linear, pre-dispensed form, if a single piece of material is used. To overcome this the device in this embodiment is formed of a series of thinner strips 102 which are joined together by fixing piece 104 at one end. In use this is the

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end which is inserted into the patient first. The thicknesses of the individual strips and their ability to move relative to one another allows them the desired degree of flexibility.

In the various embodiments as described above a single device is inserted between a pair of vertebrae to facilitate fusion thereof. In some cases, such as osteoporosis, a greater level of bearing surface needs to be provided and this can be achieved using the present invention through two or more devices being deployed between a pair of vertebrae. Three potential configurations for such deployments are illustrated in Figures 11a, 11b and 11c. In each case the main aim of minimum invasion is achieved. In Figure 11a the two devices 200 are provided in the same configuration, but alongside one another. In the Figure 11b situation the two devices 200 are provided with a part of each device within the outline of the other. In the Figure 11c situation one of the devices 200 is used to obstruct the gap between the two ends of the other device 200. Configurations such as this mechanically assist the retention of bone graft material in the fusion site.

Whilst the device can readily be used using apparatus, such as that illustrated in Figure 4, which facilitates insertion only of the device. It may be desirable in some cases, however, to be able to manipulate the device after insertion and/or to remove it. This may even include removal of the device from the spine entirely by retracting it into the apparatus. This may cause the device to assume the first state once more, from the second state. To this end Figure 12 illustrates a modified end portion 300 for a device 302 of the type described above, and a cooperating part 304 of the dispensing apparatus.

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The end portion 300 of the device 302 has a recess with a reduced width portion 306 and expanded width portion 308 which together form a dove tail. The maximum width of the portion 308 is less than the normal width 310 of the device 300 so as not to increase the extent of invasion during surgery. By providing a corresponding protrusion 312 to the dove tail in the cooperating part 304 of the dispensing apparatus a good engagement between the two can be provided.

As described above, advancing the driving part of the apparatus causes the device 302, during implantation, to be advanced into the patient, by means of the cooperating part 304 and dove tail cooperation. If the surgeon wishes to retract the device 302, however, that is possible using this type of cooperation as any retraction of the cooperating part 304 of the device results in withdrawal of the device 302. This may even include transferring the device from the second state back to the first state by withdrawing it entirely to within the surgical apparatus. Similarly manipulative movements can be conveyed from the apparatus to the cooperating part 304 and hence to the device 302 in the patient.

Various means, from simply moving the whole apparatus to retracting the cooperating part 304 into the apparatus, can be used to effect the retraction and/or manipulation of the device 302.

From the foregoing embodiments it should be clear that the invention provides a device which can have a large transverse dimension, so that the fitting of one such device in an intervertebral space should be able to suffice, it being possible for said device to be fitted through a relatively narrow slit and with a less drastic surgical intervention. It should also be clear that the device is

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constituted by a strip of memory material which may be curved in various ways, in which connection only a few of the possible embodiments are shown above by way of illustration. The term device should be taken as potentially interchangeable with the term prosthesis.

## CLAIMS

1. An intervertebral fusion device, the device comprising an elongate element, the elongate element providing one or more upper load bearing surfaces and one or more lower load bearing surfaces, the upper and lower load bearing surfaces being vertically spaced from one another by the elongate element, the elongate element having a first state and a second state, the elongate element having a substantially linear configuration in the first state and a less linear configuration in the second state, the elongate element being capable of transition, at least once, from the second state to first state and being capable of transition, at least once, from the first state to the second state, the elongate element being of shape memory alloy.
2. A fusion device according to claim 1 in which the first state provides a linear configuration for the elongate element.
3. A fusion device according to claim 1 in which the first state provides a configuration in which one end of the elongate element is further from the other end of the elongate element, measured along a straight line, than from any other part of the elongate element, the device having a waveform configuration.
4. A fusion device according to any preceding claim in which the second state provides a configuration in which at least a part of the elongate element is curved.



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5. A fusion device according to any preceding claim in which the second state provides a configuration in which at least part of the elongate element is provided as a waveform and/or undulating strip.
6. A fusion device according to any preceding claim in which in the second state the elongate element has a configuration which is a part circle and/or full circle and/or spiral and/or U-shape and/or a part oval and/or full oval.
7. A fusion device according to any preceding claim in which the elongate element has a different thickness at one or more locations along its length than at other locations along its length, the reduced thickness locations extend across the full width of the elongate element.
8. A fusion device according to claim 7 in which the reduced thickness locations are provided by grooves in the elongate element.
9. A fusion device according to claim 7 or claim 8 in which the reduced thickness portions are preferentially provided in the portion or portions of the elongate element which undergo a change in profile during the transition from first to second state compared with the portion or portions of the elongate element which undergo no or a lesser change in profile during the transition from the first to second state.

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10. A fusion device according to any preceding claim in which the elongate element has a thickness of less than 3mm.
11. A fusion device according to any preceding claim in which the maximum extent of the elongate element, measured from any point to any other in a straight line, is preferably less than 50mm, when considered in the second state.
12. A fusion device according to any preceding claim in which the elongate has a non-rectilinear cross section at one or more locations along its length, a rectilinear cross section being provided at a location between those locations of non-rectilinear cross section.
13. A fusion device according to claim 12 in which the non-rectilinear cross section provides an increased thickness portion at the upper load bearing surface and at the lower load bearing surface of the elongate element.
14. A fusion device according to any preceding claim in which the elongate element has an upper load bearing surface or surfaces and a lower load bearing surface or surfaces, the upper and lower load bearing surface and/or one or more of the upper and lower load bearing surfaces being parallel to one another.
15. A fusion device according to any preceding claim in which the elongate element has an upper load bearing surface or surfaces and / or a lower load bearing

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surface or surfaces which are provided with serrations or spikes.

16. A fusion device according to any of claims 1 to 13 in which the upper and lower load bearing surface and/or one or more of the upper and lower load bearing surfaces are angled relative to one another, the angle between a projection of the upper load bearing surfaces and/or at least one of the upper load bearing surfaces and the lower load bearing surface and/or at least one of the lower load bearing surfaces, the angle being  $5^{\circ}$  to  $15^{\circ}$ .
17. A fusion device according to any of claims 14 to 16 in which the vertical spacing of the upper and lower load bearing surface or surfaces is between 7mm and 20mm,
18. A fusion device according to any of claims 14 to 17 in which the minimum vertical spacing is preferably more than 4mm.
19. A fusion device according to any preceding claim in which the elongate element has one or more holes in it, the holes being round and / or oval and / or triangular and / or diamond shaped.
20. A fusion device according to any preceding claim in which at least one end of the elongate element is provided with an engagement profile, the engagement profile defining a dovetail.
21. A method of surgery, the method including the acts of  
:-

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making an incision in the patient;

removing at least part of an intervertebral disc from the patient through the incision, thereby providing an intervertebral disc space; and

inserting a device into the intervertebral space;

the device comprising an elongate element, the elongate element providing one or more upper load bearing surfaces for a vertebrae and one or more lower load bearing surfaces for a vertebrae, the upper and lower load bearing surfaces being vertically spaced from one another by the elongate element, the elongate element having a first state prior to insertion and a second state after insertion, the elongate element having a substantially linear configuration in the first state and a less linear configuration in the second state, the elongate element being capable of transition, at least once, from the second state to first state and being capable of transition, at least once, from the first state to the second state, the elongate element being of shape memory alloy.

22. A method according to claim 21 in which the shape memory alloy of the device is in a cold state in the first state and is in a warm state in the second state, the device being warmed, at least in part by the body heat of the patient, the warming causing the transition from cold to warm state for the memory metal of the device and hence from the first to the second state of the device.

23. A method according to claim 22 in which external heating of the device is applied, the temperature of the device in the patient being raised to at least 40°C.

24. A surgical apparatus for inserting a device into a patient, the apparatus including a holding frame for the device, a pushing element configured to enter the holding frame, at least one hand operated component, the hand operated component being indirectly or directly linked to the pushing element, operation of the hand operated component advancing the pushing element into the holding frame.
25. Apparatus according to claim 24 in which the pushing element is provided with a profile which cooperates with a portion of the device during advancement and retraction of the pushing element.
26. Apparatus according to claim 24 or claim 25 in which the holding frame is sealed at one or both ends.
27. Apparatus according to claim 26 in which the holding frame is sealed by one or more seals and the pushing element breaks a seal when advanced in to the holding frame and/or the device breaks a seal when advanced out of the holding frame.
28. Apparatus according to any of claims 24 to 27 in which the holding frame is detachable from the apparatus.
29. Apparatus according to any of claims 24 to 27 in which the apparatus has a body, the body provides a mount for the holding frame and/or at least one hand operated component and/or pushing element.

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30. An intervertebral fusion device, the device comprising an elongate element, the elongate element providing one or more upper load bearing surfaces and one or more lower load bearing surfaces, the upper and lower load bearing surfaces being vertically spaced from one another by the elongate element, the elongate element having a first state and a second state, the elongate element having a substantially linear configuration in the first state and a less linear configuration in the second state, the elongate element being capable of transition, at least once, from the second state to first state and being capable of transition, at least once, from the first state to the second state, the elongate element being formed of a plurality of elongate components which at least in part extend alongside one another.
31. A fusion device according to claim 30 in which the elongate components correspond to one another in form.
32. A fusion device according to claim 30 or claim 31 in which the elongate components are in the form of a plurality of equivalently configured strips, adjacent strips being in contact with one another.
33. A fusion device according to any of claims 30 to 32 in which the elongate components are connected together to form a single elongate element, the elongate components being connected together at one end.
34. An intervertebral fusion device, the device comprising a memory metal elongate element, the elongate element providing one or more upper load bearing surfaces and

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one or more lower load bearing surfaces, the upper and lower load bearing surfaces being vertically spaced from one another by the elongate element, the elongate element having first and second ends and a substantially non-linear configuration between the two ends.

35. A fusion device according to claim 34 wherein the elongate element has a thickness and the substantially non-linear configuration defines a radius, and wherein the thickness and radius are predetermined so that, when the elongate element is straightened to form a substantially linear configuration, no deformations of more than 8% arise.
36. A fusion device according to claim 34 or claim 35 wherein the ratio of the radius to the thickness is at least 8:1.
37. A method of using a prosthetic device, comprising the steps of :
  - a)providing the device of claim 34,
  - b)straightening the non-linear configuration of the elongate element to form a substantially linear configuration, and
  - c)inserting the straightened device into the disk space, and
  - d)curving the substantially linear configuration of the elongate element to reform the non- linear configuration.
38. A device produced by :
  - a)providing the device of claim 34,

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b) straightening the non-linear configuration of the elongate element to form a substantially linear configuration, and

c) curving the substantially linear configuration of the elongate element to reform the non-linear configuration.



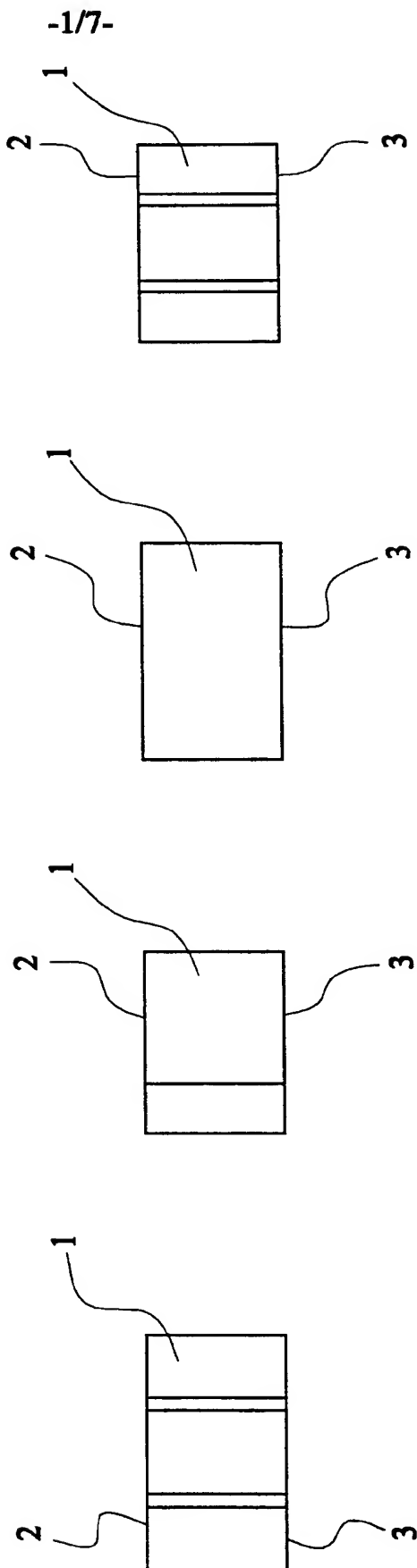
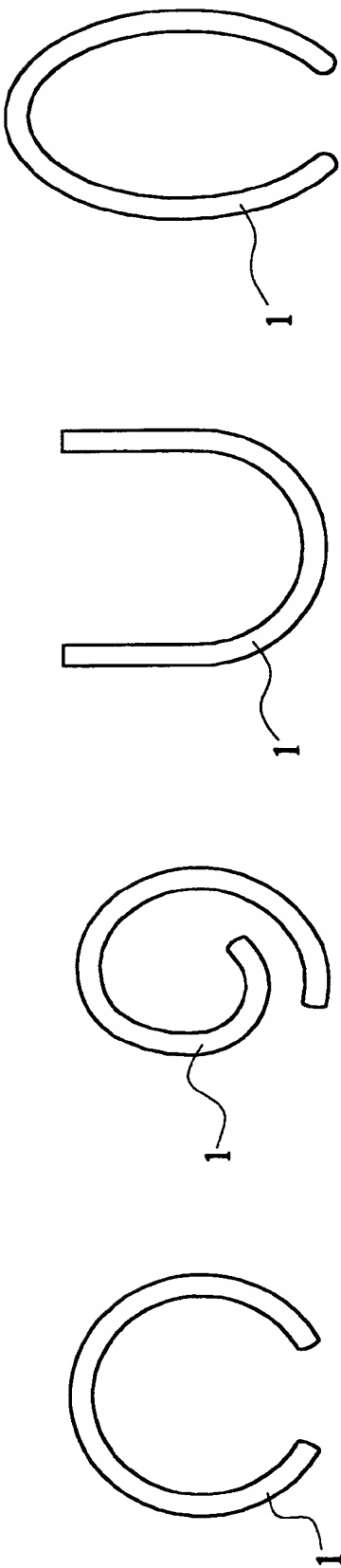


FIG. 1a

FIG. 1b

FIG. 1c

FIG. 1d

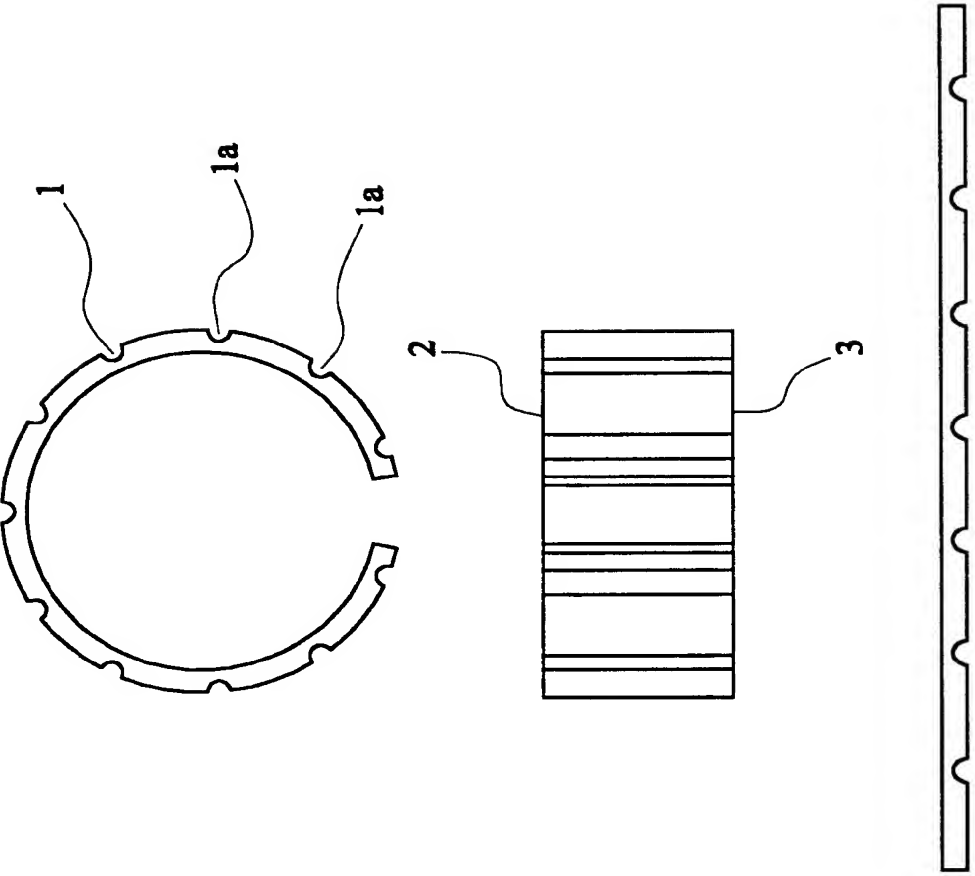


FIG. 1f

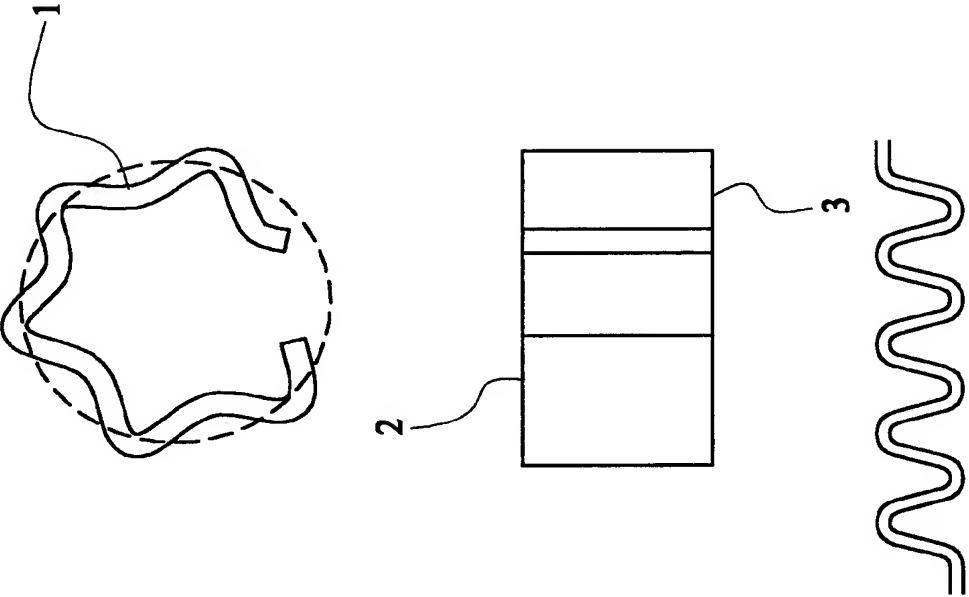
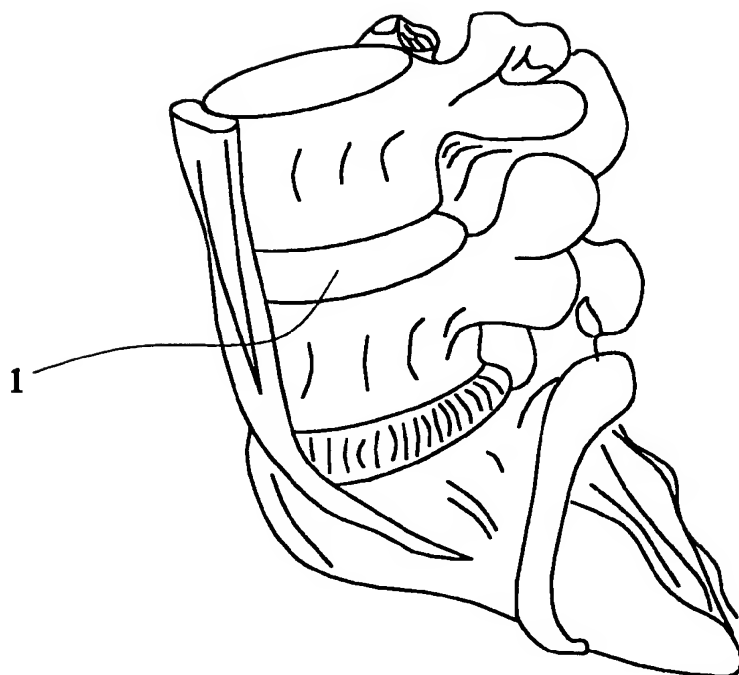
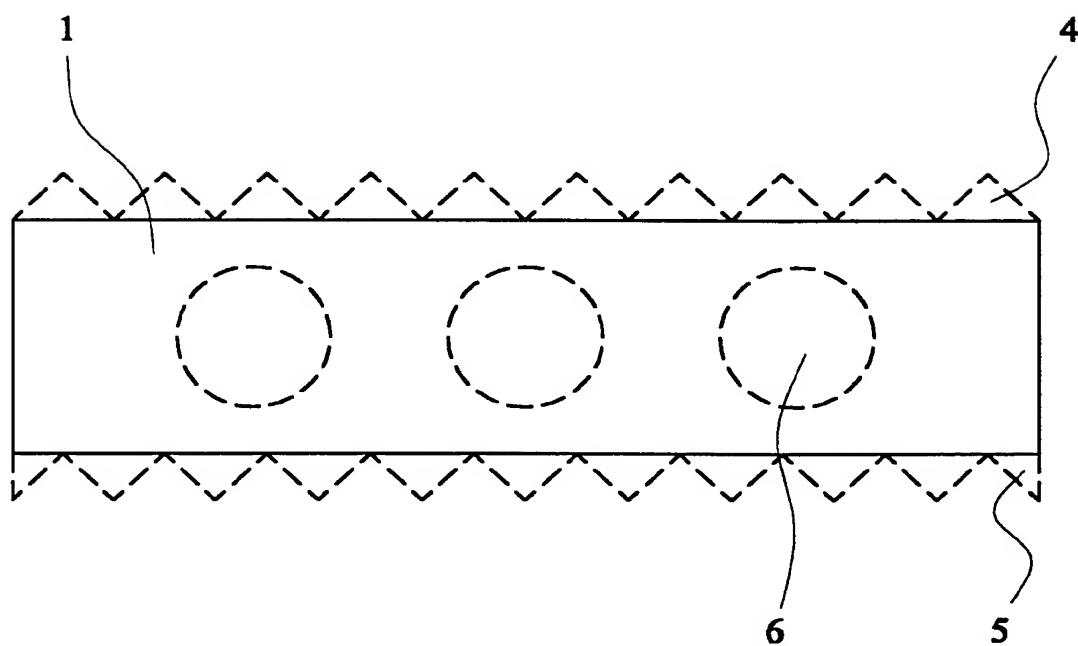
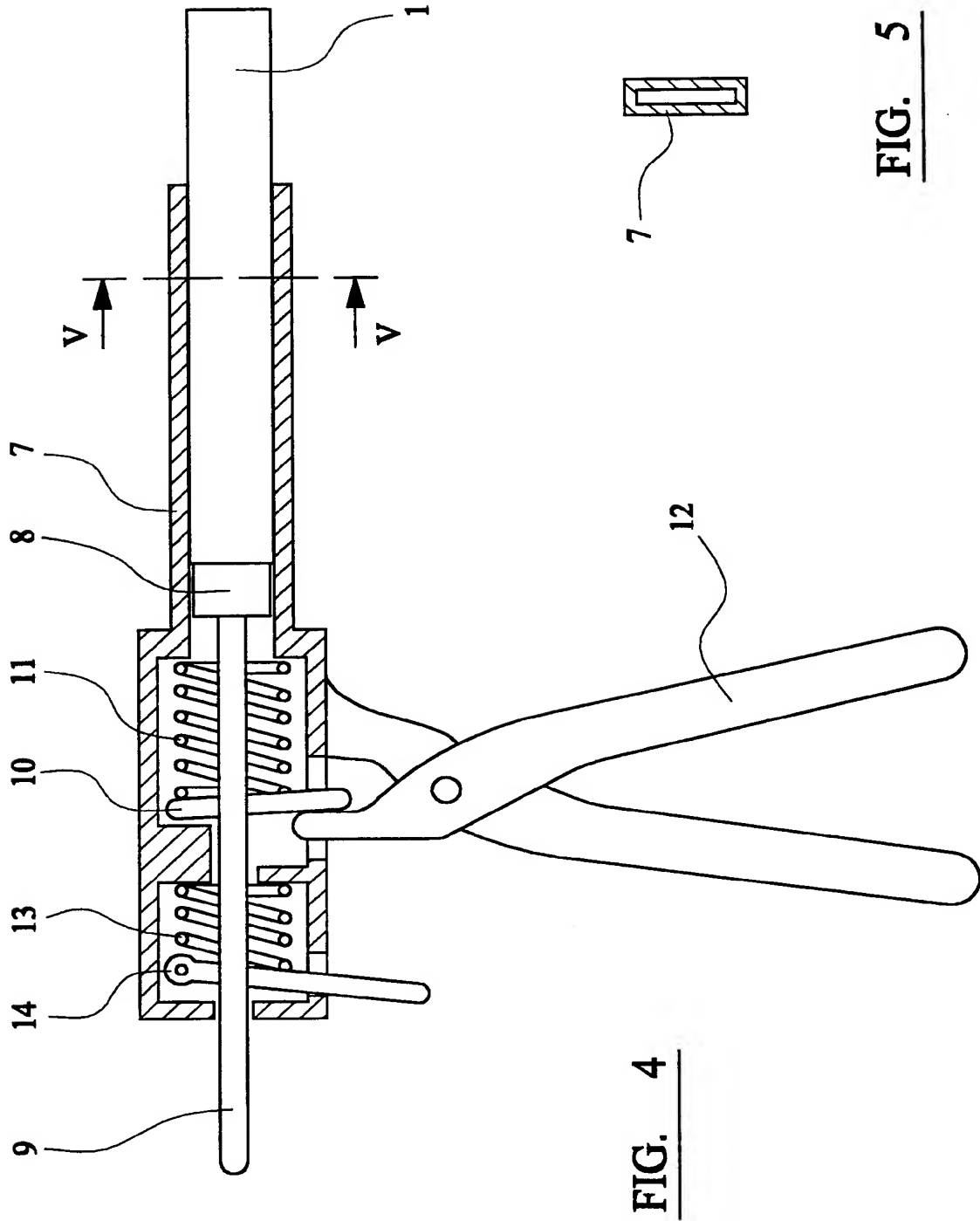


FIG. 1e

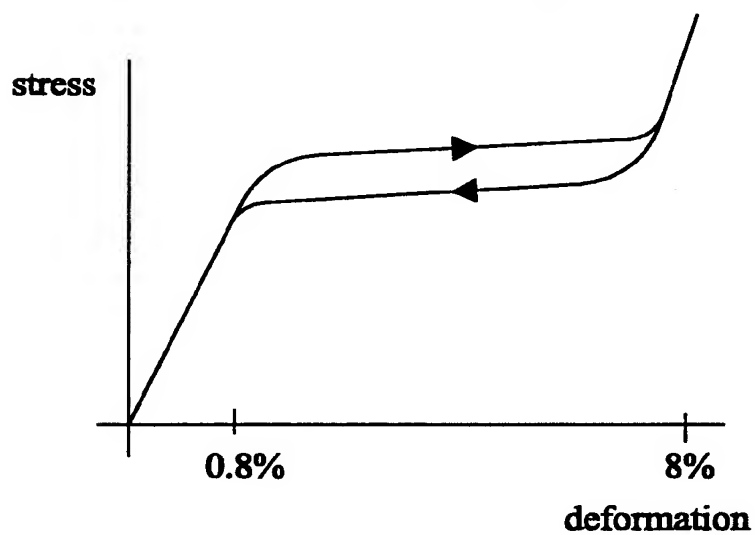
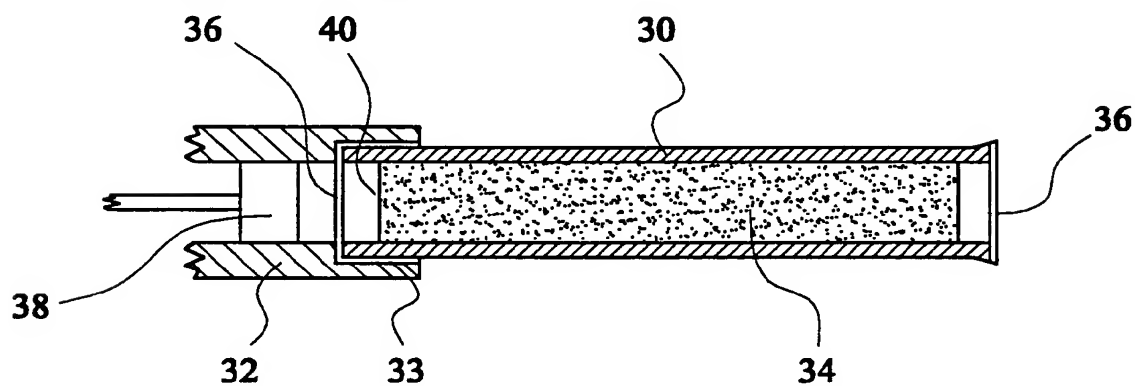
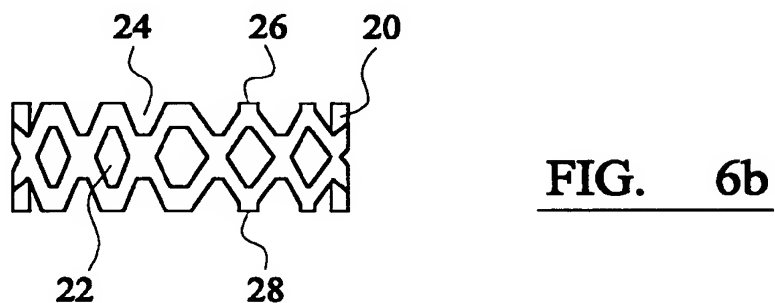
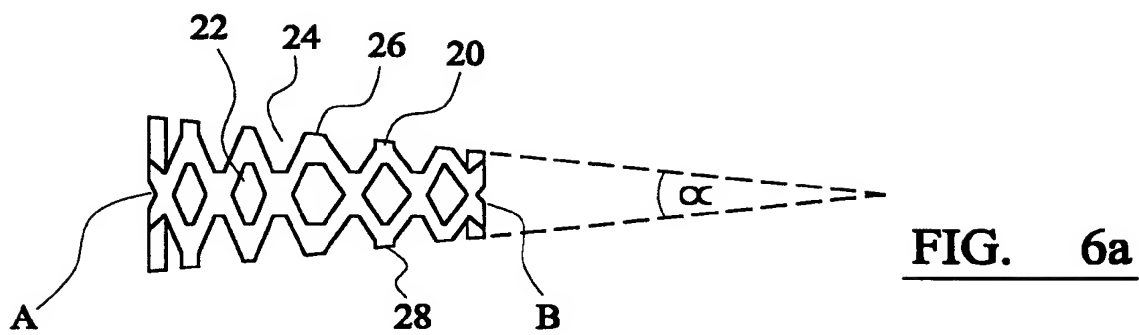
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FIG. 2FIG. 3

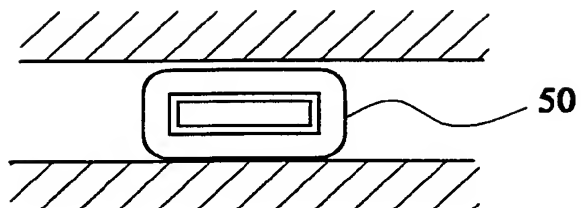
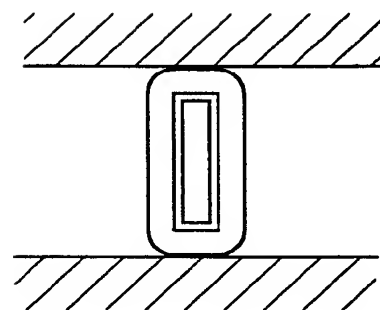
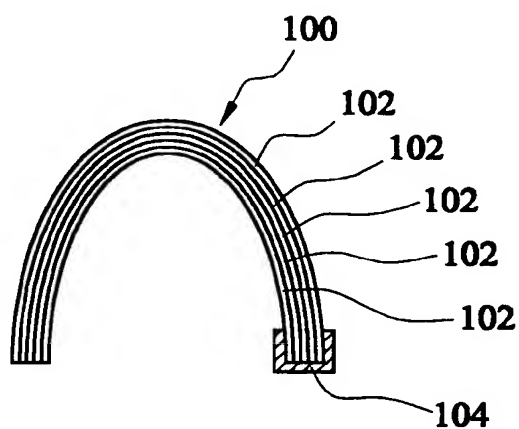
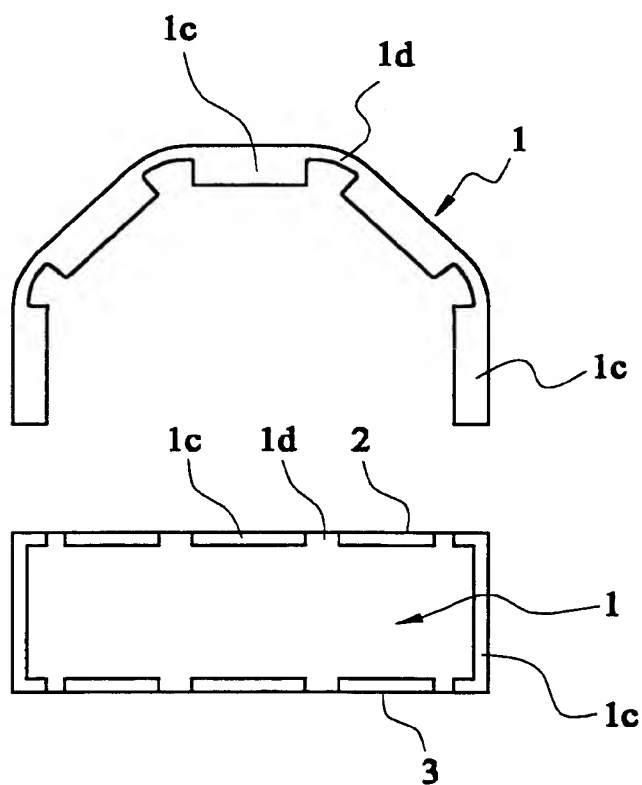
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FIG. 9aFIG. 9bFIG. 10FIG. 1g

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FIG. 11a

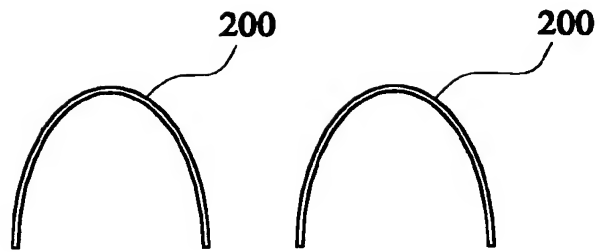


FIG. 11b

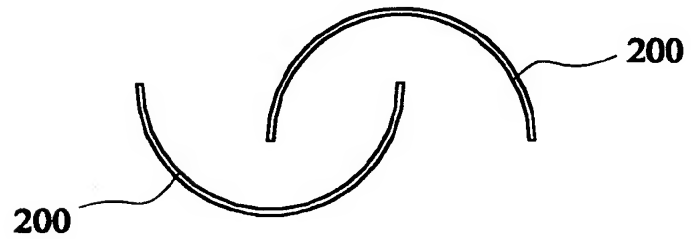


FIG. 11c

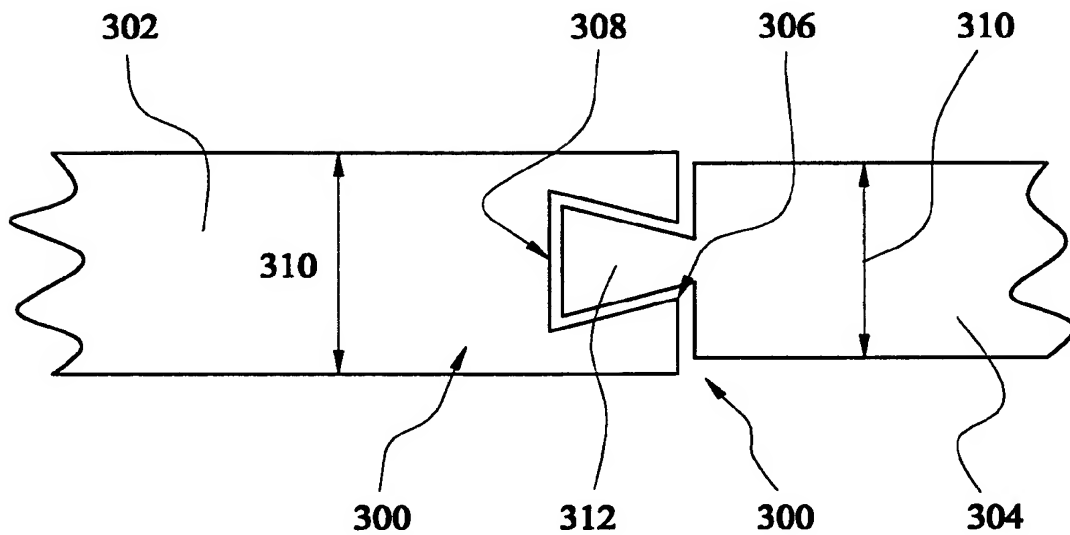
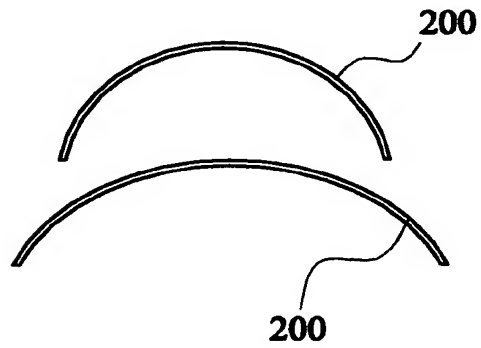


FIG. 12

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/02861

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.        |
|------------|---|------------------------------|
| X          | US 5 716 416 A (LIN CHIH-I)<br>10 February 1998 (1998-02-10)<br><br>figures 1A-E<br>column 2, line 26 -column 4, line 67<br>claim 1 | 1,2,4,6,<br>12,14,<br>24,25  |
| Y          |   | 7,15,16,<br>19               |
| A          |   | 10,11,<br>13,17,<br>18,26-38 |
|            | ---   |                              |
|            | -/--  |                              |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|------------|---|-----------------------|
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| A          | -----   | 8,9,30,<br>34         |
| Y          | WO 98 56319 A (SDGI HOLDINGS INC ;MCKAY<br>WILLIAM F (US))<br>17 December 1998 (1998-12-17)<br>figure 13<br>page 11, line 25 -page 12, line 15<br>page 13, line 29 - line 32      | 15,16,19              |
| A          | -----   | 30,34                 |
| A          | EP 0 743 045 A (GAZZANI ROMOLO IGINO<br>;SHABOLDO OLEG PAVLOVICH (RU))<br>20 November 1996 (1996-11-20)<br>figures 32,34<br>column 2, line 44 - line 48<br>claim 1                | 1,30,34               |
| A          | -----<br>US 5 609 637 A (HARMS JUERGEN ET AL)<br>11 March 1997 (1997-03-11)<br>figures 1-3<br>claims 1,2<br>-----   | 1,30,34               |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/02861

| Patent document<br>cited in search report |   | Publication<br>date | Patent family<br>member(s)  | Publication<br>date  |
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- (72) Inventors; and
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(54) Title: SEMI-AUTOMATIC COATING SYSTEM AND METHODS FOR COATING MEDICAL DEVICES

(57) Abstract: A semi-automated coating system for providing medical devices with antimicrobial coatings is disclosed. The semi-automated coating system extends the coating solution's usable life span by minimizing exposure to light, air and temperature extremes. Moreover, the disclosed semi-automated coating system minimizes operator and environmental exposure to the coating solutions. Methods disclose techniques for preparing coating solutions, setting up the coating system and operating the device. Moreover, the systems and methods described herein minimize operator intervention with the coating processes and provide superior product consistency.



WO 02/09786 A2

## SEMI-AUTOMATIC COATING SYSTEM AND METHODS FOR COATING MEDICAL DEVICES

### FIELD OF THE INVENTION

The present invention generally relates to methods and systems for coating medical devices. Specifically, the present invention relates to systems and methods for automating batch processing of medical devices in a closed system. More specifically, the present invention provides semi-automated methods and systems for coating implantable medical devices with antimicrobials using closed systems that maintain coating solution integrity, increase product throughput and minimizes personnel and environmental exposure to the coating solution.

### BACKGROUND OF THE INVENTION

Localized and systemic infections represent one of the most serious post surgical complications. Over the past fifty years tremendous advances in materials, training and antimicrobial therapies have significantly reduced the number of life-threatening post operative infections. The development of pre-sterilized disposable surgical dressings, medical instruments, gowns, drapes and other materials have helped reduce infection frequency. However, the development of improved antimicrobials represents the single most significant advance in infection control.

There are essentially three categories of antimicrobial agents: antiseptics, disinfectants and antibiotics. Antiseptics are generally defined as compounds that kill or inhibit the growth of microorganisms on skin or living tissue. Antiseptics include, but are not limited to, alcohols, chlorhexidine, iodophors and dilute hydrogen peroxide. Disinfectants are compounds that eliminate pathogenic microorganisms from inanimate surfaces and are generally more toxic, and hence more effective, than antiseptics. Representative disinfectants include, but are not limited to, formaldehyde, quaternary ammonium compounds, phenolics, bleach and concentrated hydrogen peroxide. Antibiotics are compounds that can be administered systematically to living hosts and exhibit selected toxicity, that is, they interfere with selected biochemical pathways of microorganisms at concentrations that do not harm the host. In the alternative, an ideal antibiotic will target specific metabolic pathways that are essential for the parasite, but absent in the host. Antibiotics generally work using one of four basic mechanisms of action: 1) inhibition of protein synthesis; 2) inhibition of cell wall synthesis; 3) interference with nucleic acid synthesis; and 4) altering cell membrane selective permeability. Antibiotics include, but are not limited to penicillins, aminoglycosides, tetracyclines and macrolides,

The fundamental difference between antiseptics, disinfects and antibiotics is the ability of microorganisms to develop resistance to antibiotics. The characteristics that make antiseptics and disinfectants so effective generally precludes the development of resistant microorganisms. However, disinfectants are unsuitable for use on living tissues and many antiseptics are primarily limited to localized, generally topical, applications. Consequently, most antimicrobial prophylactic and therapeutic regimens rely on antibiotics.

The microorganism's susceptibility to an antimicrobial and the ability of the antimicrobial to reach the infection site are the two most significant factors that determine antimicrobial therapy efficacy. Antimicrobial susceptibility is generally determined by culturing the organism in the laboratory and testing it against a panel of candidate drugs. However, laboratory testing can only be done if the agent causing the infection is known. When antibiotics are used prophylactically, as is the case with surgical patients, physicians generally prescribe drugs targeted to suppress the growth of the most common post surgical infectious agents. One of the most common organisms associated with surgical infections is *Staphylococcus aureus*. In the past, penicillin class drugs were considered the drugs of choice to thwart *S. aureus* infections. However, recently, many new antibiotic resistant microorganisms including penicillin resistant *S. aureus* have emerged making post surgical infection control even more challenging. Consequently, physicians have turned to new generations of antibiotics in response to emerging resistant strains.

Until recently, methicillin, an analogue of penicillin, was the preferred drug for treating and preventing penicillin resistant *S. aureus* infections. However, methicillin resistant *S. aureus* (MRSA) are becoming increasingly more common. Therefore, newer and more effective treatments for MRSA as well as other difficult to treat post surgical infections are in great demand.

One approach to treating and preventing the emergence of antibiotic resistant bacteria such as MRSA is to use two or more antimicrobial compounds in combination. The advantages to this approach include having a second antimicrobial present to inhibit resistant sub-population emergence during treatment and the potential for antimicrobial synergy. Antimicrobial synergy occurs when the efficacy of one antimicrobial is enhanced by another such that the total antimicrobial effect is greater than either one alone. In many cases either antimicrobial used separately may not completely eradicate the infection, but when the drugs are used in combination, powerfully efficacious antimicrobial regimens result.

However, even the most sensitive microorganisms cannot be killed by antimicrobials unless they can reach the infection site (antimicrobial bioavailability). Numerous factors

determine antimicrobial bioavailability including route of administration, clearance rates from the body, tissue solubility, and the degree of blood flow surrounding the infected site. Antimicrobials that are susceptible to destruction by digestive fluids, or drugs not easily absorbed in the intestines, must be administered parenterally (usually intravenously). However, regardless of the administration route, the antibiotic must survive circulation through the blood stream prior to reaching the treatment site. If the liver or kidneys rapidly removes an antimicrobial from the blood stream, or if the antimicrobial has a high affinity for blood proteins such that it is bound and inactivated by the blood, its bioavailability can be significantly reduced. This is especially true if the infection site is deep within tissues or organs that have minimal blood flow.

Deep tissue infections can result when medical implants become contaminated prior to surgical placement. When oral or parenterally administered antimicrobials fail to effectively control and eliminate the infection, the medical implant may have to be removed. Removal requires additional surgical procedures to treat the infection and re-implant the device after the infection completely resolves. Moreover, once deep tissue infections are established, long term antimicrobial therapy and hospitalization may be required. These additional procedures increase the costs associated with device implantation, subject the patient to discomfort and in rare circumstances, increase the threat of permanent disfigurement.

Coating implantable medical devices with antimicrobial compounds provides a technique for deep tissue drug delivery that can significantly reduce the risk of post implantation infections. Coating procedures should employ broad spectrum antimicrobials that are effective against most post surgical infections, especially MRSA infections. The antimicrobials need to be soluble in physiological fluids and must be stable enough to survive processing steps required to successfully coat the medical device. Ideally, a synergistic antimicrobial combination should be used. Non-limiting examples of antimicrobial combinations are described in United States Patent Numbers (USPNs) 5,624,704 and 5,902,283, the entire contents of which are herein incorporated by reference. Moreover, the antimicrobial coating procedure must employ methods and materials that are compatible with the antimicrobial and the material used to make the medical device. Medical devices, specifically implantable types, can be fabricated from a wide variety of biocompatible compounds including metals and polymers. Each material presents its own unique challenges to material scientists when it is necessary, or desirable, to coat medical devices with bioactive materials. However, all coating methodologies share common objectives including the need to maximize expensive and labile coating solutions, minimize environmental contamination,

provide the medical device with an even coating, and maintain an efficient, controlled process that complies with Federal Food and Drug Administration (FDA) Good Manufacturing Practices (GMP). Tedious manual methods of batch coating medical devices cannot achieve these goals for all medical devices on a consistent basis.

5           The size, shape and composition of the medical devices can significantly limit manual methods. Moreover, lot-to-lot consistency, GMP compliance and product throughput are all greatly enhanced when automated, or semi-automated, processes are involved. Moreover, non-automated processes subject expensive coating solutions to contamination and excessive waste resulting from spillage and product handling. Additionally, many polymeric compounds used  
10   to make medical devices are coated using harsh and often toxic solvent mixtures in order to imbibe the coating material into the devices. Exposure to these solvents poses a potential risk to personal, equipment and the environment that can be best minimized by coating in a closed system, a process incompatible with most manual methods.

          Therefore, there is a need for methods and systems that can provide implantable  
15   medical devices with antimicrobial coatings. Moreover, there is a need for methods and systems that can provide antimicrobial coatings in a closed system that reduce exposure to toxic solvents, maintain coating solution integrity for prolonged periods, allow for maximum product throughput, provide the medical device with a consistent, even coating, minimize product handling and accomplishes these goals in an FDA GMP compliant manner.

## 20   SUMMARY OF THE INVENTION

          It is an object of the present invention to provide a self-contained, automated system for coating a medical device with a antimicrobials.

          It is another object of the present invention to provide antimicrobial coating systems and methods that extend the usable life expectancy (pot life) of the coating solution by limiting  
25   the solution's exposure to atmospheric conditions including light and air.

          It is still another object of the present invention to provide antimicrobial coating systems and methods that extend the pot life of the coating solution by minimizing thermal exposure.

          It is another object of the present invention to provide antimicrobial coating systems  
30   and methods that protect the operator and the environment from the coating solution.

          It is yet another object of the present invention to provide antimicrobial coating systems and methods that are automated and minimize user intervention.

It is another object of the present invention to provide implantable medical devices having antimicrobial coatings that reduce post implantation infections by releasing antimicrobial compounds into the surrounding tissues for sustained time periods.

The coating solutions of the present invention are composed of antimicrobial compounds including, but not limited to, antiseptics and antibiotics dissolved in potentially toxic organic solvents. These solutions are extremely expensive to prepare and are easily inactivated by exposure to temperatures above ambient, air (specifically reactive oxygen species), light (specifically ultraviolet light) and contamination. Therefore, maximizing the pot life requires precise temperature control and protection from air, light and contamination. The methods and systems of the present invention accomplish these and other goals and simultaneously reduce the manufacturing environment's exposure to potentially toxic coating solutions. (It is important to distinguish the coating solutions from coated medical devices. The coating solutions of the present invention are highly concentrated mixtures of antimicrobial compounds and solvents. These mixtures may be toxic to manufacturing professionals exposed to large concentrations. However, the coated medical device, when used in accordance with the manufacturer's directions for use and under the supervision of a qualified physician, present minimal or no risks to the patient).

The present invention provides methods and systems that permit medical devices to be safely coated with antimicrobial compounds while maximizing pot life. However, the systems and methods of the present invention can be used to coat any device safely and efficiently with a wide range of different compounds and are not limited solely to providing medical devices with antimicrobial coatings.

The use of the term "coating" is not intended as a limitation and includes any physical or chemical method of providing the surfaces, or polymeric matrices, of medical devices with antimicrobial properties. Non-limiting examples of such chemical and physical methods include impregnation, imbibing, ionic interactions, covalent bonds, van der Waals forces, hydrogen bonding, protein-protein interactions, antibody-antigen complexes, resin coatings, electrodeposition, plasma deposition or the like. Hence the term coating is not to be construed narrowly to mean merely a surface layer, but should be interpreted to include providing a homogeneous concentration or gradient of antimicrobials throughout a medical device's body.

The present inventors have determined that optimum coating of medical devices occurs when the coating solution is heated to temperatures that significantly accelerate the degradation of the coating solution. In order to optimize the coating process and simultaneously maximize the solution's pot life, the coating solutions of the present invention are preheated in a holding



vessel before being transferred to a processing vessel containing the medical devices. Any coating solution remaining in the holding vessel is cooled to ambient temperatures or below while the processing vessel containing the antimicrobial solution and medical device is held at a constant elevated temperature. At the conclusion of a predetermined optimum processing  
5 time, the coating solution is transferred from the processing vessel back to the holding vessel where it is cooled to ambient temperatures or below. This entire process is conducted in a sealed system that protects the coating solution from exposure to damaging environmental factors, reduces solvent evaporation and isolates manufacturing personnel from the solution.

After the medical device has been coated it is aerated for a predetermined time period  
10 using a pressurized gas flow (sparging system) and then washed at least once using a wash solution that is pumped into the closed processing vessel and gently agitated using the sparging system of the present invention. After washing is completed, a gas, usually air, is passed over the medical device using the sparger to accelerate the drying process. The device is then removed from the sealed system and packaged prior to terminal sterilization.

15 The entire process of the present invention is under the control of a programmable microprocessor/controller that receives a series of imputes from remotely located sensors. Each sensor monitors an event and continually notifies the microprocessor/controller of its status. Should any sensor detect an out-of-range condition, the system will either fail to initiate the next step or abort the process while simultaneously notifying an operator of a default  
20 situation.

In one embodiment of the present invention the self-contained coating system is attached to a containment platform to collect and confine accidental coating solution spills. Attached to the containment platform is at least one temperature controller consisting of either a heater, a chiller or a combination thereof, a holding vessel a processing vessel and at least  
25 one fluid transfer system. The fluid transfer system moves coating solution between the holding and the processing vessels and/or wash solution to and from the processing vessel. In one embodiment of the present invention there are a plurality of fluid transport systems each directing the flow of different fluids between the holding vessel and processing vessel and/or fluid reservoirs.

30 In one embodiment of the present invention the holding and processing vessels are fitted with sealable closures and at least one mixing device for maintaining uniform antimicrobial solution and for preventing thermal gradients from forming. The processing vessels of the present invention are also fitted with a sparging system that provides a gas flow into the processing tank during the aeration, washing and drying steps. In one embodiment of

the preset invention the gas flow velocity may be adjusted to optimize the particular process step.

In another embodiment of the present invention the antimicrobial coating system includes one or more valve assemblies located at various points along the fluid transfer systems and gas lines. Additionally, numerous sensors may be located on the holding vessel, the processing vessel, vessel closures, the heat transfer devices, the fluid transfer systems, and temperature controllers. Each sensor feeds information to a programmable microprocessor that controls contents, temperatures, fluid levels, and gas flow within the holding and processing vessels. The programmable microprocessor of the present invention can also be adapted to open and close valves and act as a fail-safe monitor responsive to remote sensors.

In another embodiment of the present invention a method for coating a medical device is provided. This method includes providing a sealable first vessel filled with a coating solution and a sealable second vessel containing a medical device to be coated. The coating solution in the first vessel is preheated to a temperature appropriate for the coating process and then transferred to the second preheated vessel. Any coating solution remaining in the first vessel is cooled to at least ambient temperature and the coating solution in the second vessel is held at a constant coating process temperature until the processing interval is complete. At the conclusion of the processing interval the coating solution in the second vessel is transferred back to the first vessel and cooled.

The coated medical device is then aerated, after which the wash solution is transferred into the second vessel and the medical device is washed while gas is gently sparged into the wash solution. After a predetermined period the wash solution is removed and the wash step is repeated as many times as desired. After washing is complete the medical device is dried using a higher velocity of sparged gas. The entire method can be automated by providing a microprocessor/controller responsive to at least one remote sensor.

Other objects and features and advantages of the present invention will be apparent to those skilled in the art from a consideration of the following detailed description of preferred exemplary embodiments thereof taken in conjunction with the Figures which will first be briefly described.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a block diagram that depicts the general coating process in accordance with the teachings of the present invention.

FIG. 2 depicts the basic components of the coating system of the present invention.

FIG. 3 depicts one embodiment of a product suspension device used in accordance with the teachings of the present invention.

FIG. 4 depicts one embodiment of the gas sparger used in accordance with the teachings of the present invention.

5        FIG. 5 depicts the control panel of the microprocessor/controller of the present invention.

FIG. 6 depicts the compressed gas flow and gas vents used in one embodiment of the present invention.

10       FIG. 7 schematically depicts coating solution transfer between the holding vessel and processing vessel in accordance with the teachings of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

Deep tissue infections associated with *in vivo* medical devices occasionally occur when a medical device is accidentally contaminated with pathogenic or opportunistic microorganisms prior to implantation. Accidental contamination can occur if the integrity of the product packaging is compromised after terminal sterilization, or if the product contacts a contaminated surface after being removed from its packaging immediately prior to implantation. If the contaminated medical device is implanted, the microorganism may begin to proliferate in the tissues surrounding the implanted device, resulting in an infection.

20       Generally, systemic antibiotics are administered prior to surgery and continued for an additional seven days or more. However, systemic antibiotics may not always prevent the establishment of deep tissue infections. For example, an organism will continue to multiply unabated if it is resistant to the antibiotics being administered, or if the antibiotic does not reach the infection site in concentrations required to kill the organism. Recently, temporary medical devices such as catheters having antimicrobial coatings that are released in effective concentrations for sustained periods have been employed to help prevent post implantation infections. However, the antimicrobial coating solutions used are extremely expensive and generally require coating procedures that rely on elevated temperatures and toxic solvents in order to obtain uniform stable coatings.

30       Standard manufacturing practices rely on batch containing techniques that involve manually transferring the coating solutions into processing tanks and heating the solution to process temperature. The medical devices are immersed in the heated coating solution for a predetermined time and then removed from the processing tank and manually washed. The coating solution is maintained at coating temperatures for the duration of the manufacturing

shift and then discarded due to antimicrobial thermal breakdown and solvent evaporation. Consequently, large quantities of antimicrobials and solvents are used each time a medical device batch is coated. The cost and waste associated with batch processing techniques is easily amortized when thousands of small medical devices are coated in a single batch.

5 However, large bulky medical devices that displace large volumes of coating solution cannot be economically coated using batch methods. Moreover, large quantities of potentially toxic solvents are required to batch coat bulky medical devices. This results in increased material and solvent disposal costs, excessive personnel and environmental exposure and reduced product consistency.

10 The present invention provides methods and systems that significantly extend the useable life span of a coating solution (pot life) and facilitate the safe and efficient processing of large quantities of medical devices. The present invention is particularly well adapted to processing large quantities of bulky medical devices with increased economy and safety.

15 The term "coating" used herein is not intended as a limitation and is not to be construed as a process that merely covers or saturates a medical device's surface. Rather, the term coating is defined as any method, chemical or physical, that provides a medical device with antimicrobial properties, including, but not limited to, the medical device's exterior surfaces and/or internal matrices.

20 The coating solutions of the present invention can be used to provide medical devices with antimicrobial properties utilizing a variety of physical and chemical interactions between the device and the coating materials. In one embodiment of the present invention polymeric compounds, such as, but not limited to, silicones, polyolefins and polyesters can be impregnated with the antimicrobial coatings through an imbibing process. Imbibing occurs when a polymer is suspended in a solvent mixture that swells the polymer matrix carrying  
25 solutes present in the solvent into the polymer itself. After the polymer has been removed from the solvent the polymer matrix returns to its pre-swollen configuration, trapping solute molecules within the polymer. In the present invention solute molecules include antiseptics and/or antibiotics. Other physical and chemical processes may be used to provide homogeneous concentrations or antimicrobial concentration gradients to medical devices of the  
30 present invention. The chemical and/or physical makeup of the medical device dictates the optimum process.

In one embodiment of the present invention antimicrobial compounds are dissolved in organic solvents that swell the polymer causing the antimicrobials to be carried into the polymer matrix, trapping them within after the device is removed from the solvent. The

present inventors have determined that this process is particularly valuable when providing delicate thin-walled silicone medical devices with antimicrobial coatings. In one embodiment of the present invention solvent exposure was limited to approximately 30 minutes at a temperature of approximately 35°C. This process impregnates silicone devices with effective amounts of antibiotics while preserving the integrity of the silicone polymer matrix.

The coating system of the present invention is composed of a holding vessel for storing and preheating the coating solution, a processing vessel for coating, aerating, washing and drying medical devices, a fluid transfer system for transporting coating and wash solutions between the vessels and reservoirs, a temperature controller that heats and cools the solutions, a gas sparging system to facilitate aerating, washing and drying, solution mixers and a microprocessor/controller that automates the entire process. In one embodiment of the present invention the entire system is coupled to a containment platform that confines accidental coating solution spills and prevents contamination of the manufacturing environment with potentially toxic solvents.

The present invention can be used to coat medical devices made from any biocompatible material including but not limited to metals and synthetic and natural polymers. Non-limiting examples include stainless steel, nickel, titanium, silver, gold, platinum, aluminum and alloys thereof, natural rubber latex, synthetic latexes, silicone, polyolefins, and polyesters. In one embodiment of the present invention the coating solution is composed of solvents including, but not limited to butyl acetate, methyl alcohol, amyl acetate, benzene, carbon tetrachloride, chloroform, diethyl ether, ethylene dichloride, hexane, 2-ethyl hexanol, hexyl ether, methyl ethyl ketone (MEK), methyl isobutyl ketone, methylene chloride, perchloroethylene, Stoddard solvent (mineral spirits), toluene, trichloroethylene, xylene and combinations thereof.

The solvent chosen must be compatible with the medical device and the antimicrobial. The antimicrobial must be soluble in the solvent system selected and not denatured once dissolved. Polyolefin, polyester and silicone medical devices are generally used with solvent systems that swell the polymer's surface, permitting the solvent to carry the antimicrobial into the polymer's surface (imbibe). However, the solvent should not destroy the polymer's functional characteristics. After the medical device is removed from the solvent/antimicrobial mixture the device is allowed to regain its functional properties during the aeration, washing and drying steps.

In one embodiment of the present invention the medical device is composed of silicone and the solvent system is a butyl acetate and methanol blend. The antimicrobials are first

dissolved in the methanol and then the butyl acetate is added; the resulting mixture is used to imbibe the antimicrobial into a silicone medical device. After a predetermine coating interval, the solvent/antimicrobial mixture is removed and the silicone medical devices of the present invention are washed then dried. Silicone medical devices are easily softened when exposed to swelling solvents such as butyl acetate. Immediately after the solvent is removed the silicone devices are extremely fragile and can be easily broken if handled in an aggressive manner.

In one embodiment of the present invention the fragile coated medical devices are aerated using sparged gas immediately after the coating solution has been returned to the holding vessel. the aeration process continues for a predetermined time sufficient to allow structural integrity to return to the polymer. At the conclusion of the aeration process the medical devices of the present invention are washed.

Wash fluids are added to the processing vessel gently to avoid disturbing the devices. In one embodiment of the present invention the washing fluid enters the processing vessel through a port near the vessel top and is deflected downward along the vessel sides. In another embodiment of the present invention the wash fluids slowly fill from the vessel's bottom. Washing is facilitated by sparging a low velocity gas stream into the wash fluid via a sparge system located at the vessel's base. This low velocity gas sparge gently agitates the wash solution to aid in removing excess antimicrobial deposits that accumulated on the product during coating. During the washing process the silicone devices of the present invention continue to regain firmness and become increasingly resistant to tearing and deformation. Final polymer integrity is restored as the medical devices are dried in the processing vessel under a stream of sparged gas.

The present inventors have determined that the aeration, washing and drying processes of the present invention are greatly enhanced when gas is sparged into the processing vessel during these steps. Gas is provided to the process vessel sparger using either compressed gas cylinders or a remote gas compressor. The gas used may be, but is not limited to, air, nitrogen, argon or other minimally reactive gases or gas mixtures. In one embodiment of the present invention the sparger is a spiral shaped device made from stainless steel or other non-reactive alloys and is sealed to the processing tank's bottom. Gas can be passed through the sparger at variable rates controlled by either the microprocessor/controller of the present invention or manually. In one embodiment of the present invention the gas is used at one velocity during aeration and drying steps and a second, lower velocity during the washing step. The gas is vented to the outside through a series of gas lines connected to a valve located near the vessel

top. The venting mechanism of the present invention may also provide one or more high-efficiency particulate air (HEPA)/volatile organic compound (VOC) filtration systems.

The antimicrobial solutions used in accordance with the teaching of the present invention are composed of heat labile antimicrobials such as, but not limited to, antibiotics and antiseptics. These labile antimicrobial compounds are extremely expensive and need to be dissolved in volatile solvents including, but not limited to, water, alcohols, ketones, ethers, esters and aldehydes. When batch-coating techniques are employed the coating solutions of the present invention are exposed to above ambient temperature conditions that accelerate the thermal breakdown of the antimicrobials. Moreover, open, or partially sealed, containers are often used to prepare the solutions and coat the medical devices. These containers may expose the coating solution to ultraviolet light and air that further accelerate antimicrobial breakdown and promote volatile solvent evaporation. As the solvents evaporate and the compounds deteriorate, the exact concentration of biologically active coating material changes and the coating solution begins to discolor. Medical devices coated using the deteriorated solutions have unknown biological activity and are cosmetically unattractive. Consequently, the deteriorated coating solution must be destroyed and a new solution prepared before further coating can occur.

In one embodiment of the present invention the coating solution is continuously maintained under an inert atmosphere. After the antimicrobial coating solution has been prepared as described in Example 1 below, an inert gas, such as, but not limited to, bone-dry nitrogen is injected into the holding tank such that air present in the holding tank is displaced through a vent located near the holding vessel's top above the fluid level.

In another embodiment a sparging apparatus is incorporated into the bottom of the holding vessel through which the inert gas is introduced. Inert gas is also provided to the entire coating system including all gas lines, fluid paths, fluid transfer systems and the processing tank. In this embodiment the entire coating system remains under an inert atmosphere until the system is opened to air. The holding vessel containing coating solution is continually maintained in an inert atmosphere and remains sealed until such time as a new batch of coating solution is prepared. As the fluid level within the holding vessel is reduced during coating solution transfer to the process vessel, inert gas is pumped into the holding vessel to prevent a partial vacuum from forming therein. In one embodiment of the present invention inert gas displaced from the filling process vessel is transferred to the emptying holding vessel. In another embodiment inert gas is vented out of the filling process vessel and inert gas is provided to the emptying holding vessel from an inert gas reservoir. However, the process of

providing inert gas to emptying vessels and removing inert gas from filling vessels will depend on the coating system configuration and any such processes are considered within the scope of the present invention. Engineers of ordinary skill in the art would be capable of configuring a suitable gas transfer system consistent with the teachings of the present invention.

The coating systems and processes of the present invention provide improved coating solution stability and enhanced operator safety by employing a sealed, semi-automated system having the capacity to maintain coating solutions at temperatures that improve stability, reduce evaporation and prevent atmospheric contamination. The coating solutions of the present invention are heated to coating temperature for a minimum period and then cooled to holding temperature until the next coating cycle is initiated.

Examples of medical devices that can be coated using the systems and methods of the present invention include, but are not limited to, catheters, surgical slings, artificial joints penial implants, ocular implants, stents, suture and heart valves.

FIG. 1 depicts the process 100 of the present invention in a generalized block diagram. The semi-automated process of the present invention begins 101 when the coating solution stored 124 at or below ambient temperature in the holding vessel is heated to process temperature 102. Product is transferred 104 into the processing vessel and the cycle is initiated 106 when the coating solution reaches process temperature. Coating solution is pumped 108 into the holding vessel 108 and the product is coated for a predetermined time 110. Any coating solution remaining in the holding vessel is cooled to ambient temperature or below. At the conclusion of the coating step the coating solution is pumped back into the holding vessel and cooled 112. The coated product remaining in the processing vessel is aerated 116 to provide time for the swollen product matrix to reform, and/or for the coating material to fully imbibe. The product is washed 118 using a wash solution and gentle agitation from sparged gas. At the completion of the wash step 120 the wash fluid is drained from the processing vessel and the wash step is repeated 120a, or the product is removed from the process vessel and dried 122. In another embodiment of the present invention the product 121 is dried in the processing vessel.

Turning now to FIG. 2. The coating system of the present invention is generally depicted at 200 and is composed of a holding vessel 202 for storing the coating solution at or below ambient temperature and for preheating the coating solution to a predetermined process temperature. In one embodiment of the present invention the coating solution is preheated in the holding vessel 202 using a circulating heater 206. The circulation heater 206 cycles a heat



transfer fluid through thermal jackets that envelop holding vessel **202** and processing vessel **204**. Circulation control valves **208a** and **208b** facilitate heat transfer fluid circulation. The coating solution in holding vessel **202** is continually mixed using an overhead low shear mixer **210** to prevent the formation of thermal gradients and to keep the coating solution in a homogenous state.

Holding vessel **202** is fitted with a first sealable closure **212** that prevents solvent evaporation, minimizes contamination and reduces environmental exposure to the coating solution. Product to be coated is suspended in processing vessel **204** using devices and methods known to those skilled in the art. A non-limiting example of a product suspension device is depicted in FIG. 3 at **300**. After the product has been securely loaded into processing vessel **204**, second sealable closure **218** is secured. The proper sealing of closure **218** is detected by the process vessel closure sensor **220** that is in electronic communication with microprocessor/controller **216**.

The coating cycle is initiated by engaging cycle initiate button **214** on microprocessor/controller **216**. Microprocessor/control **216** will not allow the coating process to begin unless inputs from solvent temperature sensor **222**, process vessel closure sensor **220** and process latch sensor **224** indicate the coating solution is at processing temperature and the process vessels closure **218** is closed and latched. The coating process begins as pre-heated coating solution is transferred from holding vessel **202** by pump/direction valve network **226** into process vessel **204**.

The treatment timer **228** is activated when fluid level sensor **230** detects a level of coating solution sufficient to cover the product. At the initiation of the treatment period holding vessel **202** is isolated from circulation heater **206** and circulation cooler **232** begins circulating cooled heat transfer fluid through holding vessel's **202** thermal jacket. The coating solution in processing vessel **204** is maintained at coating temperature and continually mixed using a magnetically coupled mixer **234** located at process vessel's **204** base. Mixing maintains an even elevated temperature throughout the coating solution in the processing vessel and remains engaged as long as treatment timer **228** is active.

At the completion of the treatment period, pump/direction valve network **226** reverses direction and coating solution in process vessel **204** is pumped back into holding vessel **202**. Circulation cooler **232** continues circulating cooled heat transfer fluid through holding vessel's **202** thermal jacket to cool returning coating solution to ambient temperature or below. After all remaining coating solution is removed from processing vessel **204** an aeration cycle is initiated.

During the aeration cycle gas passes through filter 242 and into processing vessel 204 through sparger (see FIG. 4 at 402) connector to process vessel's 204 bottom through gas line 246. The filtered gas passes over the coated product and out of process vessel 204 through gas line 244. High velocity gas regulator 236 that is responsive to microprocessor/controller 216 controls aeration gas flow velocity. The aeration period is regulated by aeration timer 238 located and under the control of microprocessor/controller 216. At the completion of the aeration cycle microprocessor/controller 216 shuts off the gas flow and engages wash fluid pump system 248 that provides wash fluid from wash fluid reservoir 250 to process vessel 204 through fluid supply line 252.

Wash fluid level is monitored by fluid level sensor 230 that is responsive to microprocessor/controller 216. After the preset wash fluid level is reached microprocessor/controller 216 shuts off wash fluid valve 248 and engages low velocity gas regulator 254. The low velocity gas flows through filter 242 and into processing vessel 204 through sparger (see FIG. 4 at 402) connector to process vessel's 204 bottom through gas line 246.

Wash timer 240 responsive to microprocessor/controller 216 regulates the wash interval. When wash timer 240 times out, microprocessor/controller 216 closes vent valve 260 and low velocity gas provided through sparger (see FIG. 4 at 402) pressurizes process vessel 204. Vessel out valve 256 and drain valve 258 are opened by the microprocessor/controller 216 and wash fluid exits processing vessel 204. The entire wash procedure can be repeated as many times as desired as herein described. The washed product can be removed from process vessel 204 at the completion of the wash step(s), or dried in sealed process vessel 204 using a high velocity air flow as describe for the aeration step above.

The present invention can be made from any assortment of materials compatible with the intended solutions and processes. In one embodiment of the present invention the holding vessel 202, processing vessel 204, and all associated metallic components that contact product or the coating solution are made entirely of stainless steel. Valve seats, seals, and fittings that contact coating solution are composed of, but not limited to Teflon® and Delrin®, (Teflon® and Delrin® are products made by E.I. du Pont de Nemours and Company of Wilmington, Delaware).

The inventors of the present invention have determined that sparging gas into processing vessel 204 during one or more process steps 100 (FIG.1), including, but not limited to post-coating, pre-wash step (aeration) 116, the washing process 118 and as an adjunct to drying 121 significantly improves coating consistency and appearance. Any number of gas

sources can be used including, but not limited to air, nitrogen helium, argon or any combination therefore. In one embodiment of the present invention compressed air is provided to the coated products through a sparger 402 (FIG. 4) located near the bottom of processing vessel 204. Compressed gas passes through filter 242 having a mean porosity of between approximately 0.1 $\mu$ m to 10 $\mu$ m, preferably between approximately 0.5 $\mu$ m and 2 $\mu$ m, more preferably 0.7 $\mu$ m to 1.0 $\mu$ m, before entering sparger 402. The novel spiral shape of sparger 402 provides a vortex motion to the air current or wash fluid depending on the process cycle. The present inventors believe that the vortices significantly increases the sparger's efficiency and provides for a gentle, but thorough, agitation during the wash cycle.

The valves of the present invention that control the fluid and gas flow can be electronically or pneumatically activated. In one embodiment of the present invention the valves are pneumatically activated Teflon® seated ball valves. In other embodiments of the present invention electromechanical valves could be used. However, when potentially flammable solvents are used with the coating system of the present invention electromechanical valves present the potential for igniting the solvents. Consequently, the present inventors have chosen to use the more versatile and generally safer pneumatic activated valves. Electronic solenoid valves isolated in microprocessor/controller 216 control the pneumatically activated valves of the present invention. When a solenoid receives an output signal from microprocessor/controller 216 it opens, sending pressurized gas to the valves. The valves of the present invention remain open as long as pressurized gas flows to the valve. The gas flow is shut off and the valve closes when the output device controlling the valve receives a close command from the microprocessor/controller 216.

Turning now to FIG. 5. The microprocessor/controller of the present invention can be any programmable microprocessor known to those of ordinary skill in the art that can receive, process, store and relay data to and from remote sensors and electromechanical devices. The microprocessor/controller inputs of the present invention include, but are not limited to, cycle start button 502, cycle abort button 504, treatment timer 506, solvent temperature 508, reset button 510, process level sensor 512, high level sensor, solution flow sensor 514, aeration timer 516, wash timer 518, manual drain key switch 520, process vessel cover sensor, process vessel latch sensor, manual pump forward 522, manual pump reverse 524, manual pump mode 526. The inputs depicted in FIG. 5, and other inputs of microprocessor/controller 500 can include any number of different options depending on the functions that are to be automated and conditions to be monitored.

Once data has been received and processed by microprocessor/controller 500 output devices responsive to microprocessor/controller 500 control the coating system 200 (FIG. 2) and coating process 100 (FIG. 1). Output devices of the present invention can be any type known to those of ordinary skill in the art. The output commands used to control the coating system 200 (FIG. 2) of the present invention include, but are not limited to, pump motor on/off, pump motor direction valves, holding vessel out valve, process vessel out valve, low pressure drain gas supply, drain valve open/closed, holding vessel to processing vessel vent, process complete indicator 528, sight glass vent valve, wash fluid on, reset hold signal for treatment timer, circulation cooler/heater control, aeration valve on, main system vent, aeration timer enable, wash timer enable.

The inputs and outputs of the present invention work in a coordinated fashion to control and monitor the coating system and process of the present invention. Table 1 illustrates the coordinated interaction of the inputs and outputs of one embodiment of the present invention. It is understood that there are many other input/output combinations and those presented in Table 1 are not meant to limit the present invention, but merely to provide one example. The corresponding input and output abbreviations used in Table 1 are defined in Tables 2 and 3 immediately following Table 1.

Table I

| Step | Process Step Description                 | Inputs On                   | Outputs On                            |
|------|--|-----------------------------|---------------------------------------|
| 0    | Standby, vessels closed, rest            | I-3, II-3, II-4             | II-2                                  |
| 1    | Start cycle, pump to process vessel      | I-0 mom, I-3, II-3, II-4    | I-0, I-1, I-2, I-3, I-6, II-2         |
| 2    | Process level reached, processing        | I-3, I-5, II-3, II-4        | I-1, II-3                             |
| 3    | Process time elapsed, pumping back to HV | I-2, I-7, II-3, II-4        | I-0, I-2, I-3, I-6, II-3              |
| 4    | Back to holding vessel, aeration time on | I-2, II-3, II-4             | II-0, II-3, II-4, II-5, II-6          |
| 5    | Aeration done, rinse water fill to level | I-2, II-0, II-3, II-4       | II-1, II-3, II-5, II-6                |
| 6    | Full, bubble wash time                   | I-2, I-5, II-0, II-3, II-4  | II-3, II-4, II-5, II-6, II-7          |
| 7    | Dump rinse, blow down                    | I-2, II-0, II-1, II-3, II-4 | I-3, I-4, I-5, II-3, II-6, II-7       |
| 8    | Refill rinse to level                    | I-2, II-0, II-3, II-4       | I-5, II-1, II-3, II-5, II-6           |
| 9    | Full, 2 <sup>nd</sup> wash cycle         | I-2, I-5, II-0, II-3, II-4  | I-5, II-3, II-4, II-5, II-6, II-7     |
| 10   | Dump 2 <sup>nd</sup> rinse, blow down    | I-2, II-0, II-1, II-3, II-4 | I-3, I-4, I-5, II-3, II-6, II-7       |
| 11   | Cycle complete, in process dry cycle on  | I-2, II-0, II-1, II-3, II-4 | I-4, I-5, I-7, II-3, II-5, II-6, II-7 |
| 12   | Process cycle complete, vessel open      | I-2, II-0, II-1             | I-5, I-7, II-3, II-6, II-7            |
| 13   | Controller reset, cover open, temp low   | I-4 mom (reset in)          | I-2                                   |

## NOTES:

Step 2 Input I-3 (Temp Alarm Off) may go off momentarily due to reaction time of the cold process vessel sensor being warmed by the incoming solution.

Step 3 Input I-3 (Temp alarm Off) may be On or Off due to cooling of the Holding Vessel. Controller becomes a HV temp monitor only.

Step 4 Inputs I-5 and I-6 (Sightglass Sensors) may be on due to condensation in the sightglass during the first minutes of aeration time.

Table II

| Input No. | Description                                  |
|-----------|--|
| I-0       | Start Cycle                                  |
| I-1       | Abort Cycle                                  |
| I-2       | Treatment Timer Time Out                     |
| I-3       | Solution Temp Input                          |
| I-4       | Reset Controller                             |
| I-5       | Reactor Vessel Process Point Solution Sensor |
| I-6       | Reactor Vessel High Solution Sensor          |
| I-7       | Solution Flow Switch                         |
| II-0      | Aeration Timer Time Out                      |
| II-1      | Bubble Wash Timer Time Out                   |
| II-2      | Manual Drain Valve On                        |
| II-3      | Process Vessel Cover Closed                  |
| II-4      | Process Vessel Latched                       |
| II-5      | Manual Pump On (Forward Direction)           |
| II-6      | Manual Pump On (Reverse Direction)           |
| II-7      | Manual Pump Mode On                          |

Table III

| Output No. | Description  |
|------------|--|
| I-0        | Pump Motor On  |
| I-1        | Pump Motor Direction (ON=Fwr) V <sup>1</sup> 1 & V2                          |
| I-2        | Holding Vessel Valve On, V5  |
| I-3        | Process Vessel Valve On, V6  |
| I-4        | Low Pressure Drain Air Valve (Blow Down), V10                                |
| I-5        | Drain Valve On, V4   |
| I-6        | Hld. V. to Pro. V. Vent Valve On, V7   |
| I-7        | Process Complete Indicator   |
| II-0       | Sightglass Vent Valve On, V16  |
| II-1       | Pure Water Valve On, V11   |
| II-2       | Reset Treatment Timer  |
| II-3       | HV Switch from Circ. Htr. to Cooler (Rly-2). Circ. Htr. Control to PV. Rly-1 |
| II-4       | Aeration Valve On, V8  |
| II-5       | Roof Vent (Exhaust) Valve, V3  |
| II-6       | Aeration Timer Enable  |
| II-7       | Bubble Wash Timer Enable   |

5           FIG. 6 depicts compressed gas flow and the gas vents used in one embodiment of the present invention. Compressed air 600 is provided to coating system 200 (FIG. 2) through air line 602 when valve 604 is opened. Compressed air then moves through filter 242 and into either high pressure regulator 236 and through high pressure compressed air valve 606, or through low pressure regulator 254 and through low pressure valve 608 to sparger line 610 to provide compressed air to sparger 402 in processing vessel 204.

10

<sup>1</sup> V is an abbreviation for valve and refers to the pneumatic operated ball valves used in one embodiment of the present invention.

Coating solution is pumped from holding vessel 202 to processing vessel 204 and air is displaced from processing vessel 204 and sight glass 612 through sight glass vent valve 614. Sight glass valve 614 opens in response to solenoid 616 located in microprocessor/controller 216 (FIG. 2) and air is vented out of the system through vent 618 responsive to solenoid 620.

5 Wash solution is purged from process vessel 204 by closing sight glass vent valve 614 while maintaining air flow into processing vessel 204 through sparger line 610. Air contained in holding vessel 202 is released therefrom as the coating solution is pumped from processing vessel 204 through holding vessel 202 to processing vessel vent 622 in response to solenoid 624.

10 FIG. 7 schematically depicts coating solution transfer between holding vessel 202 and processing vessel 204. Microprocessor/controller 216 initiates coating solution transfer following engagement of cycle start button 502 (FIG. 5). Solvent transfer pump 702 is activated by solenoid 704 and begins pumping coating solution from holding vessel 202 through holding vessel valve 706 in response to solenoid 708. The coating solution is pumped  
15 through pump direction valve 708 and directed towards processing vessel 204 by pump direction valve 710. Pump direction valves 708 and 710 are responsive to solenoid 714. Coating solution enters processing vessel 204 through processing valve 712 that is activated by solenoid 716. Coating solution returns to holding vessel 202 by reversing its path through pump/direction valve network 226. Drain valve 718, responsive to solenoid 720 directs  
20 coating solution flow to and from processing vessel valve 712, or can be engaged to direct wash fluids from processing vessel 204. Manual valve 722 can be engaged to drain spent coating solution from the coating system of the present invention and sample port valve 724 can be manually opened to withdraw coating solution samples for analysis. It is understood that FIG. 7 represents one embodiment of the coating solution transfer system of the present  
25 invention and that many other combinations of pumps and valves known to those of ordinary skill in the art can be employed.

Many of the solvents used in association with the coating system of the present invention can be toxic and/or flammable. Therefore, the present invention has a number of safety features. In one embodiment of the present invention a spill containment platform is  
30 integrated into the coating system. The holding vessel, processing vessel, fluid transfer systems, temperature controllers, gas vents and all fluid transfer lines are contained within the perimeter of a tray-like platform having high wall sides. The platform walls are high enough to safely contain the entire combined contents of the holding vessel, the processing vessel and

solutions contained within the fluid transfer systems. In the unlikely event that a spill should occur, the manufacturing environment itself would not be contaminated.

In another embodiment of the present invention the coating system is provided with a series of fail safe devices composed of sensors that feed back to the microprocessor/controller.

- 5     Sensor locations include, but are not limited to, holding vessel and processing vessel closures and latches, fluid level minimums and maximums, valves and vents. If the microprocessor/controller of the present invention does not receive the appropriate inputs from each sensor, the process will either fail to be initiated or aborted. Moreover, the microprocessor/controller of the present invention is provided with a prominent, easily  
10    accessible manual override that permits the operator to shut the system down should a potentially unsafe condition arise.

## **EXAMPLES**

### **Example 1**

#### **Preparation of an Antimicrobial Coating Solution**

- 15         Transfer 9.06 liters of acetone-free absolute methyl alcohol (catalogue number M 1775, Sigma Chemicals, St. Louis, MO. USA) into the holding vessel of the present invention and engage the holding vessel mixer. Slowly add 681.3 grams of USP grade Rifampin (Lupin Laboratories, LTD, Mumbai, India) to the methanol. Next, add 568 grams of USP grade Minocycline (Companhia Industrial Produtora de Antibioticos, S.A., Castanheira Do Ribatejo,  
20    Portugal) to the Rifampin/methyl alcohol mixture. After all of the Rifampin and Minocycline have dissolved, slowly added 13.63 liters of ACS reagent grade n-butyl acetate (catalogue numner B 6408 Sigma Chemicals, St. Louis, MO. USA). Immediately cover the holding vessel and secure.

**Example 2****Exemplary Coating Procedure Including Microprocessor/Controller Input/Output Sequence****Process Step 0:**

**Coating System Status:** Stand-by condition, process vessel loaded, closed and latched. Vessel  
 5 temperature 35°C.

**Input<sup>2</sup> Status:**

1. Solvent Temperature Alarm off signal from temperature controller. I-3
2. Process Vessel cover closed sensor signal. II-3
3. Process Vessel cover latched sensor signal. II-4

**10 Output<sup>3</sup> Status:**

1. Treatment Timer reset signal. II-2

**Process Step 1**

**Coating System Status:** Initiate process cycle, pumping solution to process vessel.

**15 Input Status:**

1. Initiate Cycle push button signal (momentary). I-0
2. Solvent Temperature Alarm off signal from temperature controller. I-3
3. Process Vessel cover closed sensor signal. II-3
4. Process Vessel cover latched sensor signal. II-4

**20 Output Status:**

1. Solvent Pump On. I-0
2. Pump direction signal out, (pump to process vessel from holding vessel). I-1
3. Holding Vessel Output Valve Open. I-2
4. Process Vessel Output Valve Open. I-3
- 25 5. Holding Vessel to Process Vessel Vent Valve on. I-6
6. Treatment Timer reset signal. II-2

**Process Description:**

To initiate the process cycle the microprocessor/controller must have inputs from the temperature controller (solution temperature is at process temperature), and the two process  
 30 vessel cover sensors (cover closed and latched). Once these inputs are present, the initiate cycle button will start the process cycle.

---

<sup>2</sup> See Table 2.

<sup>3</sup> See Table 3.



The controller then turns on the solvent pump, the two vessel output valves, the vessel to vessel vent valve, and the pump flow direction valves so the pump direction is from holding vessel to process vessel.

## 5 **Process Step 2**

Coating System Status: Solvent process level reached in process vessel, processing

### Input Status:

1. Solvent Temperature Alarm off signal from temperature controller. I-3
2. Process Vessel Solvent Level Sensor signal. I-5
- 10 3. Process Vessel cover closed sensor signal. II-3
4. Process Vessel cover latched sensor signal. II-4

### Output Status:

1. Pump direction signal out, (pump to process vessel from holding vessel). I-1
2. Heat control/flow switches to process vessel, stir motor on. Holding vessel (cool) II-3

15

### Process Description:

When the solution level reaches the sight glass level sensor, a signal is sent to the microprocessor/controller indicating that the process solution level has been reached. The microprocessor/controller turns off the pump, the vessel output valves, and the vessel to vessel vent valve, but leaves the pump direction valve in the holding vessel to process vessel position. The microprocessor/controller turns off the reset signal to the treatment timer allowing the timer to start timing. The microprocessor/controller also switches the valves that disconnect the circulation heater flow from the process holding vessel and maintains flow to the processing vessel. The microprocessor/controller then initiates the holding vessel cooling cycle. The magnetic stir unit motor is engaged and the circulation temperature controller switches to monitor the process vessel temperature.

20

25

## **Process Step 3**

Coating System Status: Process time elapsed, pumping solvent back to holding vessel.

### 30 Input Status:

1. Cycle Timer Timed Out signal. I-2
2. Solvent Flow Switch Output Signal. I-7
3. Process Vessel cover closed sensor signal. II-3

4 Process Vessel cover latched sensor signal. II-4

Output Status:

1. Solvent Pump On. I-0
2. Holding Vessel Output Valve Open. I-2
- 5 3. Process Vessel Output Valve Open. I-3
4. Holding Vessel to Process Vessel Vent Valve On. I-6
5. Circulation heater to process vessel, circulation cooler to holding vessel. II-3

Process Description:

10 When the Treatment timer reaches zero, a time-out signal is sent to the microprocessor/controller. The process vessel stir motor turns off. Circulation heater flows only to the process vessel.

The circulation heater temperature controller begins monitoring and displaying the holding vessel temperature. The output signal is opened so the heater element in the  
15 circulation heater turns off. The microprocessor/controller turns on the pump, the vessel output valves, and the vessel to vessel vent valve.

During the first three seconds of pumping, an internal microprocessor/controller timer delays the flow switch signal so the pump has time to start solution flow and activate the flow switch. The flow switch becomes active when the three second timer times out. When all of the  
20 solution is pumped back into the holding vessel, the pump starts pumping air. The flow switch signals the microprocessor/controller and starts the aeration cycle and timer. The microprocessor/controller starts a 10 second pump off delay timer. This pump off delay purges the air sparger of solvent and allows 10 seconds for the pump to pump the sparger purge solvent to the holding vessel. At the end of the 10 second delay, the controller turns the pump,  
25 the vessel output valves, and the vessel to vessel vent valves off.

**Process Step 4**

Coating System Status: Solvent Back to Holding Vessel, Aeration Time.

Input Status:

- 30 1. Cycle Timer Timed Out signal. I-2
2. Process Vessel cover closed sensor signal. II-3
3. Process Vessel cover latched sensor signal. II-4

Output Status:

1. Sight lass Vent On. II-0
2. Circulation heater to process vessel, circulation cooler to holding vessel. II-3
3. Aeration Valve On. II-4
- 5 4. Roof Vent Valve On. II-5
5. Aeration Timer Enable. II-6

Process Description:

As stated in the step 3 description, the loss of the flow switch signal causes the controller to start the aeration cycle. The controller turns on the high flow air valve, the roof vent valve, and the aeration timer enable signal. The aeration timer starts timing. The Sight Glass vent turns on at the end of the pump purge delay time. At the end of the sparger purge 10 second pump off delay, the pump and solution line valves turn off.

15 **Process Step 5**

Coating System Status: Aeration time elapsed, fill process vessel with wash water.

Input Status:

1. Cycle timer timed out signal. I-2
2. Aeration Timer Time Out Signal. II-0
- 20 3. Process Vessel cover closed sensor signal. II-3
4. Process Vessel cover latched sensor signal. II-4

Output Status:

1. Pure Water Valve On. II-1
- 25 2. Circulation heater to process vessel, circulation cooler to holding vessel. II-3
3. Roof Vent Exhaust Valve On. II-5
3. Aeration Timer Enable On. II-6

Process Description:

30 When the aeration timer reaches zero, a signal is sent to the microprocessor/controller, turning sight glass vent valve off, and turning on the distilled water valve. The vessel fills with pure water until the water level reaches the process level sensor on the sight glass.

**Process Step 6**

Coating System Status: Process vessel full of wash water to process level, bubble wash on.

Input Status:

1. Cycle Timer Timed Out signal. I-2
- 5 2. Process Vessel Process Level Sensor Signal. I-5
3. Aeration Timer Time Out Signal. II-0
4. Process Vessel cover closed sensor signal. II-3
5. Process Vessel cover latched sensor signal. II-4

10 Output Status:

1. Circulation heater to process vessel, circulation cooler to holding vessel. II-3
2. Aeration Air Valve On. II-4
3. Roof Vent Exhaust Valve On. II-5
4. Aeration Timer Enable On. II-6
- 15 5. Wash Timer Enable Signal. II-7

**Process Description:**

When the level reached signal from the process level sensor reaches the microprocessor/controller the water valve is turned off and the wash timer is enabled. The  
20 aeration valve, and the roof vent valve remain on to bubble wash the product.

**Process Step 7**

Coating System Status: Wash Time elapsed, Drain Process Vessel of wash water.

Input Status:

- 25 1. Cycle Timer Timed Out signal. I-2
2. Aeration Timer Time Out Signal. II-0
3. Wash Timer Time Out Signal. II-1
4. Process vessel cover closed sensor signal. II-3
5. Process Vessel cover latched sensor signal. II-4

30

Output Status:

1. Process Vessel Out Valve. I-3
2. Low Pressure Drain Air Valve On. I-4
3. Drain Valve On. I-5

4. Circulation heater to process vessel, circulation cooler to holding vessel. II-3
5. Aeration Timer Enable On. II-6
6. Wash Timer Enable Signal. II-7

## 5 Process Description:

When the wash timer reaches zero, a signal is sent to the microprocessor/controller. The microprocessor/controller turns off the high flow air valve and the roof vent valve, and turns on the low pressure air valve, process vessel output valve, and drain valve. Low pressure air blows the wash water to drain. The controller also initiates a five minute interval timer. When the internal timer times out, the microprocessor/controller turns the low pressure air and the vessel out valve off and activates a one second reset timer that resets the wash and drain timers. The three way drain valve remains in the drain position for the second wash. Process steps 5-7 repeat for a second wash/drain cycle. The reset timer disables the reset function after the first reset so the controller will end the process cycle after the second wash/drain cycle.

**Process Step 8, Repeat process steps 5, with output I-5 (drain valve) on.**

**Process Step 9, Repeat process step 6, with output I-5 (drain valve) on.**

**Process Step 10, Repeat process step 7**

## 20 Process Step 11

Coating System Status Process Cycle Complete, Dry Cycle On

### Input Status:

1. Treatment Timer time Out. I-2
2. Aeration Timer Time Out. II-0
3. Wash Timer Time Out. II-1
4. Process Vessel Closed Signal. II-3
5. Process Vessel Cover Latched Signal. II-4

### Output Status:

1. Low Press Drain Air On. I-4
2. Drain Valve. I-5
3. Process Complete Indicator Lamp. I-7
4. Circulation Cooler/Heater Flow Control. II-3
5. Roof Vent On. II-5

6. Aeration Timer Enable. II-6

7. Wash Timer Enable. II-7

**Process Description:**

5           With the 1 second Wash/Drain cycle timed out and latched, the microprocessor/controller does not reset the wash/drain cycle and the process is complete. The latched reset timer output turns on the process complete lamp at the end of the second wash/drain cycle. The low pressure drain air remains on and the roof vent opens to dry parts in the processing vessel.

**10    Process Step 12**

Coating System Status: Process Cycle Complete, Process Vessel Open, Remove Product.

Input Status:

- 1. Treatment Timer Time Out. I-2
- 2. Aeration Timer Time Out Signal. II-0
- 15       3. Wash Timer Time Out Signal. II-1

Output Status:

- 1. Drain Valve. I-5
- 2. Process Complete Indicator Lamp On. I-7
- 20       3. Circulation heater to processing vessel circulation cooler to holding vessel. II-3
- 4. Aeration Timer Enable On. II-6
- 5. Wash Timer Enable Signal. II-7

**Process Description:**

25           Unlatching the process vessel when removing product turns off the roof vent and the low pressure drain.

**Process Step 13 Controller Reset**

Input Status:

- 30           1. Reset Signal (momentary)

Output Status:

- 1. Reset Signal (Momentary)

**Process Description:**

The reset signal resets the program to the standby mode. The circulation cooler turns off and is disconnected from the holding vessel. Circulation heater flow switches back to both holding and processing vessels. Process temperature for the next coating process.

5

From the foregoing description, one skilled in the art can readily ascertain the essential characteristics of the invention and, without departing from the spirit and scope thereof, can adapt the invention to various usages and conditions. Changes in the form and substitution of equivalents are contemplated as circumstances may suggest or render expedient, and although  
10 specific terms have been employed herein, they are intended in a descriptive sense and not for purposes of limitation. Furthermore, any theories attempting to explain the mechanism of actions have been advanced merely to aid in the understanding of the invention and are not intended as limitations, the purview of the invention being delineated by the following claims.

We claim:

1. A semi-automated medical device coating system comprising:
  - a first vessel having a sealable cover, at least one mixing device and at least one heat transfer device;
  - a second vessel having a sealable cover, at least one mixing device and at least one heat transfer device, said second vessel in two-way fluid communication with said first vessel;
  - a fluid transfer system adapted to transfer fluids between said first and said second vessels;
  - a support adapted to suspend a device in said second vessel;
  - and a gas operated sparger in said second vessel adapted to transfer gas from an external gas supply into said second vessel.
2. The semi-automated medical device coating system of claim 1 wherein said coating system is a closed system substantially preventing exposure of said fluid to the ambient atmosphere or light.
3. The semi-automated medical device coating system of claim 1 further comprising a plurality of sensors cooperatively connected to said first vessel, said second vessel, said fluid transfer system, said heat transfer devices and said mixers, said sensors responsive to at least one microprocessor/controller.
4. The semi-automated medical device coating system of claim 1 further comprising at least one temperature controller responsive to said microprocessor/controller for heating and cooling said heat transfer device of said first and said second vessels.
5. The semi-automated medical device coating system of claim 1 wherein said fluid transfer system is at least one pump.
6. The semi-automated medical device coating system of claim 1 wherein said sparger is a spiral shaped device located within said second vessel.
7. A semi-automated implantable medical device coating system comprising:
  - a containment platform having at least one temperature controller;



a holding vessel fixed to said containment platform having a first sealable closure, at least one mixer and a first heat transfer device in cooperation with said at least one temperature controller;

a processing vessel fixed to said containment platform having a second sealable closure, a gas sparger, at least one mixer, a support for suspending said implantable medical device within said processing vessel and a second heat transfer device in cooperation with said at least one temperature controller;

a first fluid transfer system in cooperation with said containment platform adapted to transfer fluids between said holding vessel and said processing vessel;

a second fluid transfer system in cooperation with said containment platform adapted to transfer fluid between said processing vessel and a remote fluid reservoir and a waste reservoir;

a gas reservoir in cooperation with said gas sparger;

a plurality of valves in cooperation with said first and said second fluid transfer systems and said gas reservoir;

a plurality of sensors in cooperation with said holding vessel, said processing vessel, said first and said second sealable closure, said first and said second heat transfer device, said first and said second fluid transfer system, said plurality of valves and said at least one temperature controller;

a programmable controller responsive to said plurality of sensors.

8. The semi-automated implantable medical device coating system of claim 7 wherein said programmable controller is adapted to regulate the contents, temperatures, fluid levels, and gas flow within said holding vessel and said processing vessel.

9. The semi-automated implantable medical device coating system of claim 7 wherein said programmable controller is adapted to open and close said plurality of valves.

10. The semi-automated implantable medical device coating system of claim 7 wherein said programmable controller is adapted to act as a fail-safe monitor responsive to said plurality of sensors.

11. A method for coating a medical device comprising:  
providing a first sealed vessel having a coating solution disposed therein;

providing a second sealed vessel adapted to receive said coating solution from said first vessel, said second vessel having at least one medical device to be coated disposed therein;  
heating said coating solution and said second vessel;  
transferring at least a portion of said coating solution to said second vessel;  
cooling said first vessel and said coating solution remaining therein;  
holding said second vessel and said coating solution disposed therein at a predetermined temperature for a first predetermined time;  
transferring said coating solution from said second vessel to said first vessel at the conclusion of said first predetermined time;  
transferring a wash solution from a wash solution reservoir into said second vessel;  
washing said medical device in said wash solution for a second predetermined time;  
removing said wash solution from said second vessel;  
drying said medical device.

12. The method for coating a medical device of claim 11 further comprising:  
mixing said coating solution in said first and said second vessels.
13. The method for coating a medical device of claim 11 further comprising:  
aerating said medical device in said second vessel prior to transferring said wash solution into said second vessel.
14. The method for coating a medical device of claim 11 further comprising:  
injecting a gas into said second vessel using a gas sparger for aerating, washing and drying said medical device.
15. The method for coating a medical device of claim 14 further comprising:  
providing a first velocity gas sparge for washing and a higher second velocity gas sparge for aerating and drying said medical device.
16. The method for coating a medical device of claim 11 further comprising:  
automating said method for coating a medical device by providing and programming a microprocessor/controller adapted to receive information from at least one sensor and transmitting information necessary to control said method for coating a medical device.

17. The method for coating a medical device of claim 11 wherein said coating solution is an antimicrobial solution.
18. The method for coating a medical device of claim 17 wherein said antimicrobial solution is an antiseptic solution.
19. The method for coating a medical device of claim 17 wherein said antimicrobial solution is an antibiotic solution.
20. The method for coating a medical device of claim 19 wherein said antibiotic solution comprises minocycline, rifampin and at least one solvent.
21. The method for coating a medical device of claim 20 wherein said at least one solvent is selected from the group consisting of: butyl acetate, methyl alcohol, amyl acetate, benzene, carbon tetrachloride, chloroform, dimethyl ether, ethylene dichloride, hexane, 2-ethyl hexanol, hexyl ether, methyl ethyl ketone, methyl isobutyl ketone, methylene chloride, perchloroethylene, Stoddard reagent, toluene, trichloroethylene, xylene and combinations thereof.
22. The method for coating a medical device of claim 11 wherein said medical device is selected from the group consisting of: urinary catheters, vascular catheters, surgical slings, artificial joints, penial implants, ocular implants, stents, sutures, and heart valves.
23. An antibiotic solution for coating a medical device consisting essentially of rifampin, minocycline and at least one solvent.
24. An antibiotic solution for coating a medical device of claim 23 wherein said at least one solvent is selected from the group consisting of: butyl acetate, methyl alcohol, amyl acetate, benzene, carbon tetrachloride, chloroform, dimethyl ether, ethylene dichloride, hexane, 2-ethyl hexanol, hexyl ether, methyl ethyl ketone, methyl isobutyl ketone, methylene chloride, perchloroethylene, Stoddard reagent, toluene, trichloroethylene, xylene and combinations thereof.

25. A semi-automated medical device coating system comprising:  
a coating solution holding vessel;  
a processing vessel for coating medical devices separate from said coating solution vessel;  
a coating solution transfer system;  
a heat transfer system for heating and cooling said holding vessel and said processing vessel either simultaneously or separately;  
a mixer associated with said holding vessel and said mixing vessel;  
at least one remote sensor;  
at least one microprocessor/controller for receiving data from said at least one remote sensor and for transmitting information to said coating solution transfer system and said heat transfer system;  
a product suspension device for holding said medical device in place during coating;  
a wash solution reservoir;  
a wash solution transfer system;  
at least one valve; and  
at least one vent.
26. A method for coating a medical device comprising:  
heating a coating solution having an antimicrobial substance suspended in said solution;  
subjecting said medical device to said heated coating solution for a specified period of time;  
removing said heated coating solution from said medical device;  
leaving a sufficient amount of said antimicrobial substance on said medical device so as to inhibit infection in a patient receiving said medical device; and,  
performing at least each of the above activities through a closed system and without intervention by a human.
27. A medical device coating system comprising:  
a first receptacle, said receptacle comprised of a material capable of holding an antimicrobial substance without introducing contamination;  
a second receptacle in fluid communication with said first receptacle;

said fluid communication being substantially closed to ambient air at least during flow of fluid;

said second receptacle sized and shaped to receive at least one medical device;

an electronic controller to govern flow between said first receptacle and said second receptacle.

28. A medical device coating system comprising:

a first receptacle, said receptacle comprised of a material capable of holding an antimicrobial substance without introducing contamination;

a second receptacle in fluid communication with said first receptacle;

said fluid communication being substantially closed to ambient air at least during flow of fluid;

said first receptacle and said second receptacle being continually maintained under an inert gas;

said second receptacle sized and shaped to receive at least one medical device;

and

an electronic controller to govern flow between said first receptacle and said second receptacle.

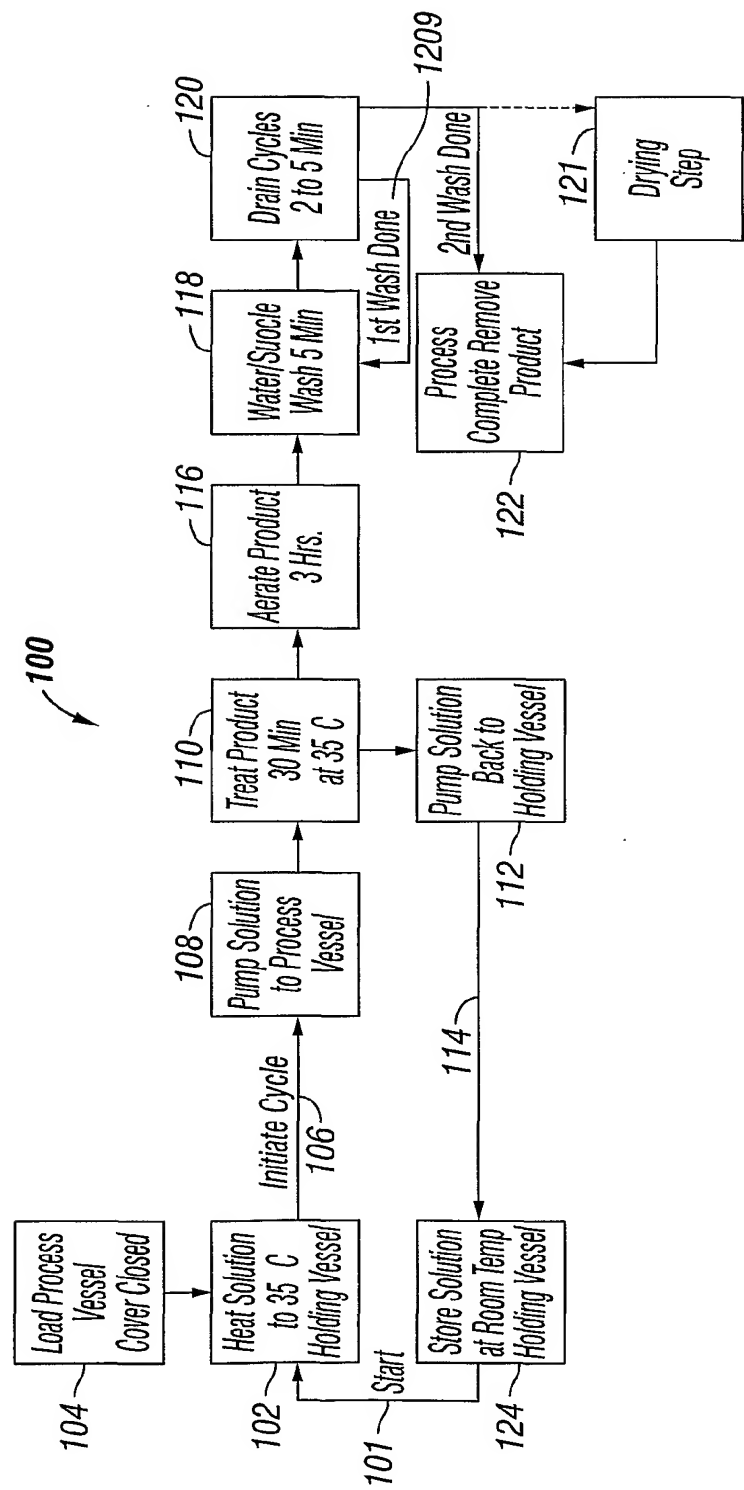


FIG. 1

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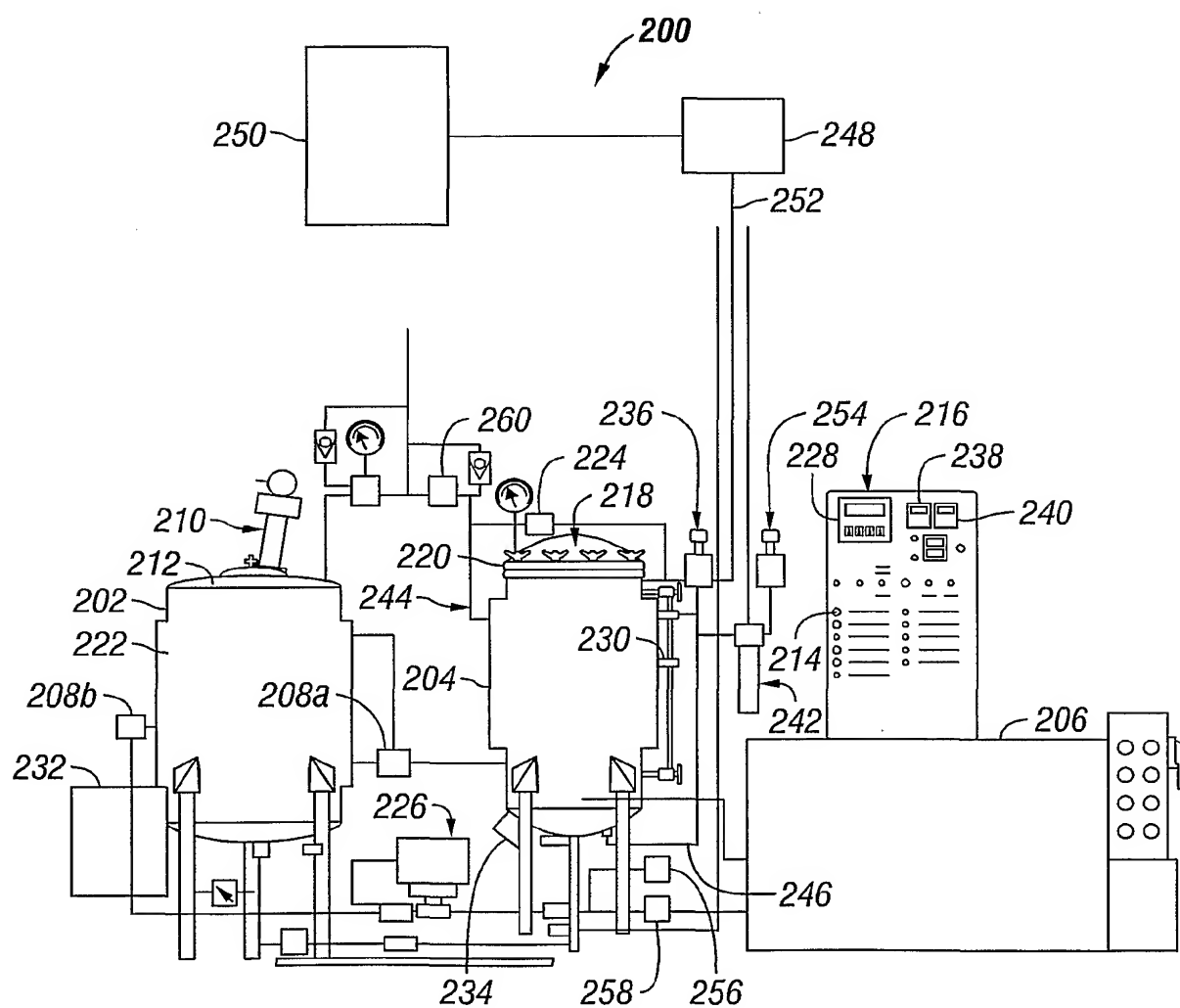
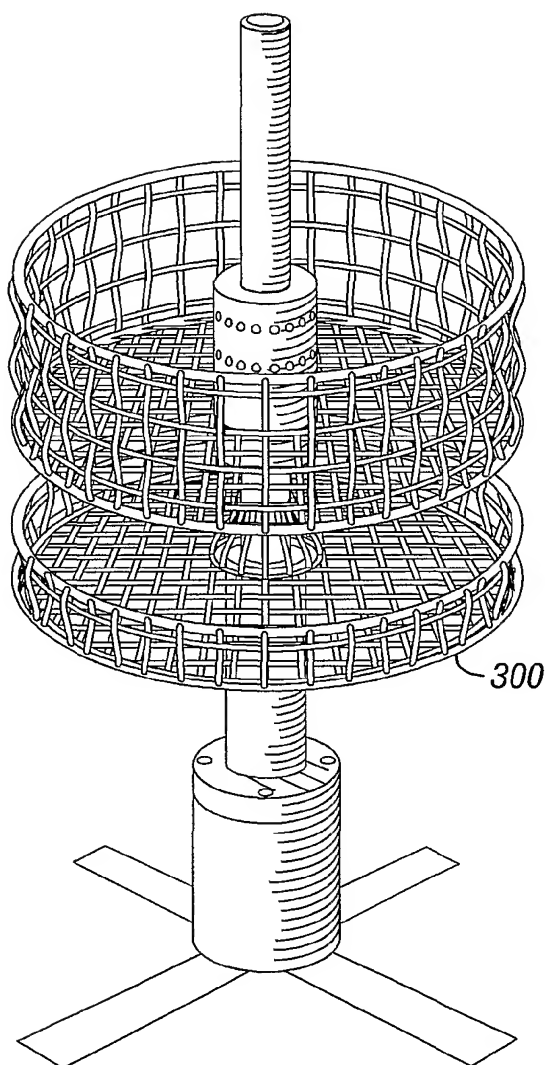


FIG. 2

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**FIG. 3**



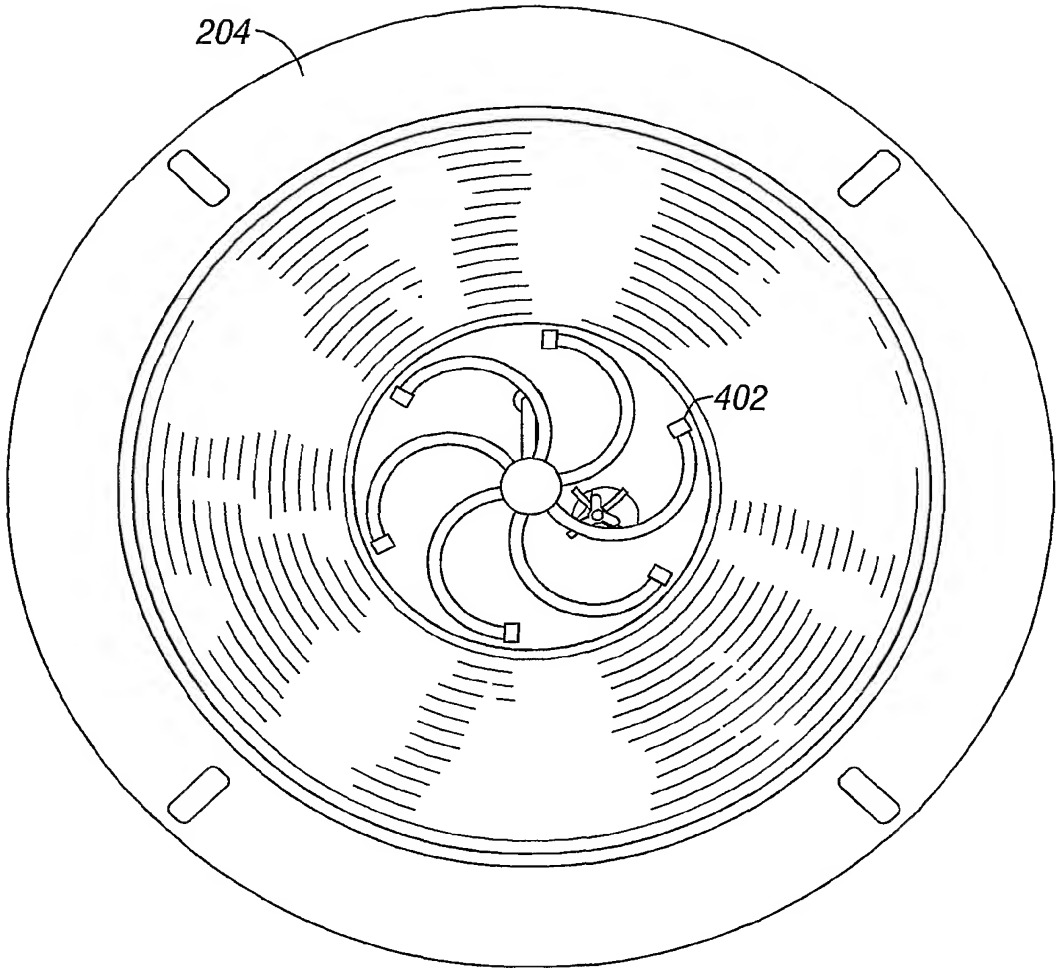


FIG. 4

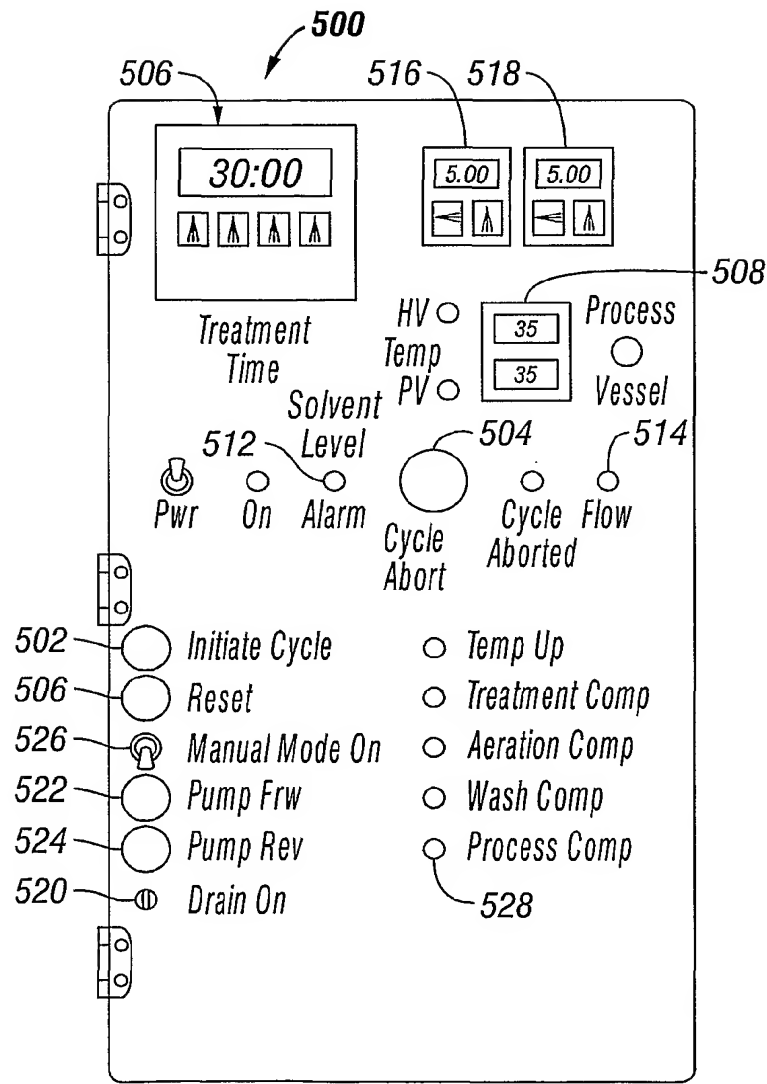
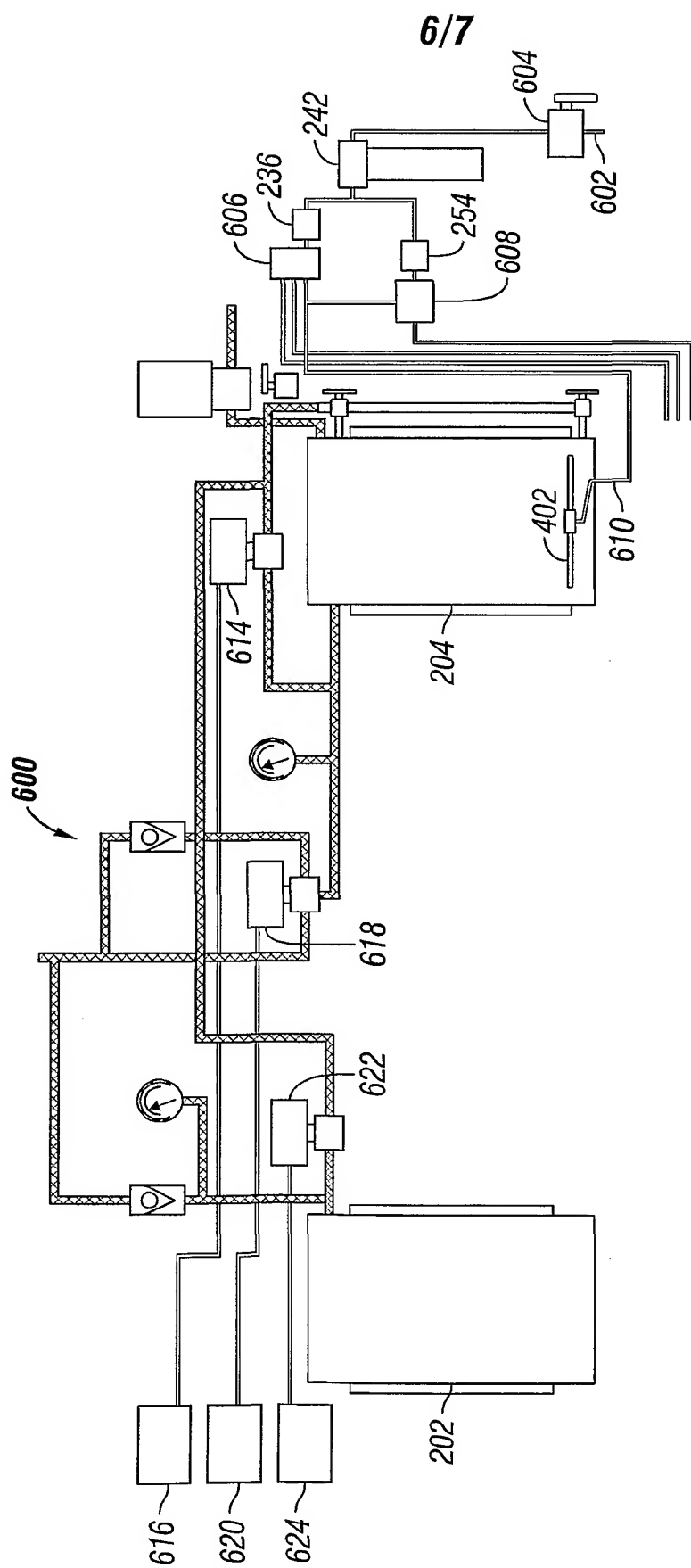


FIG. 5



**FIG. 6**

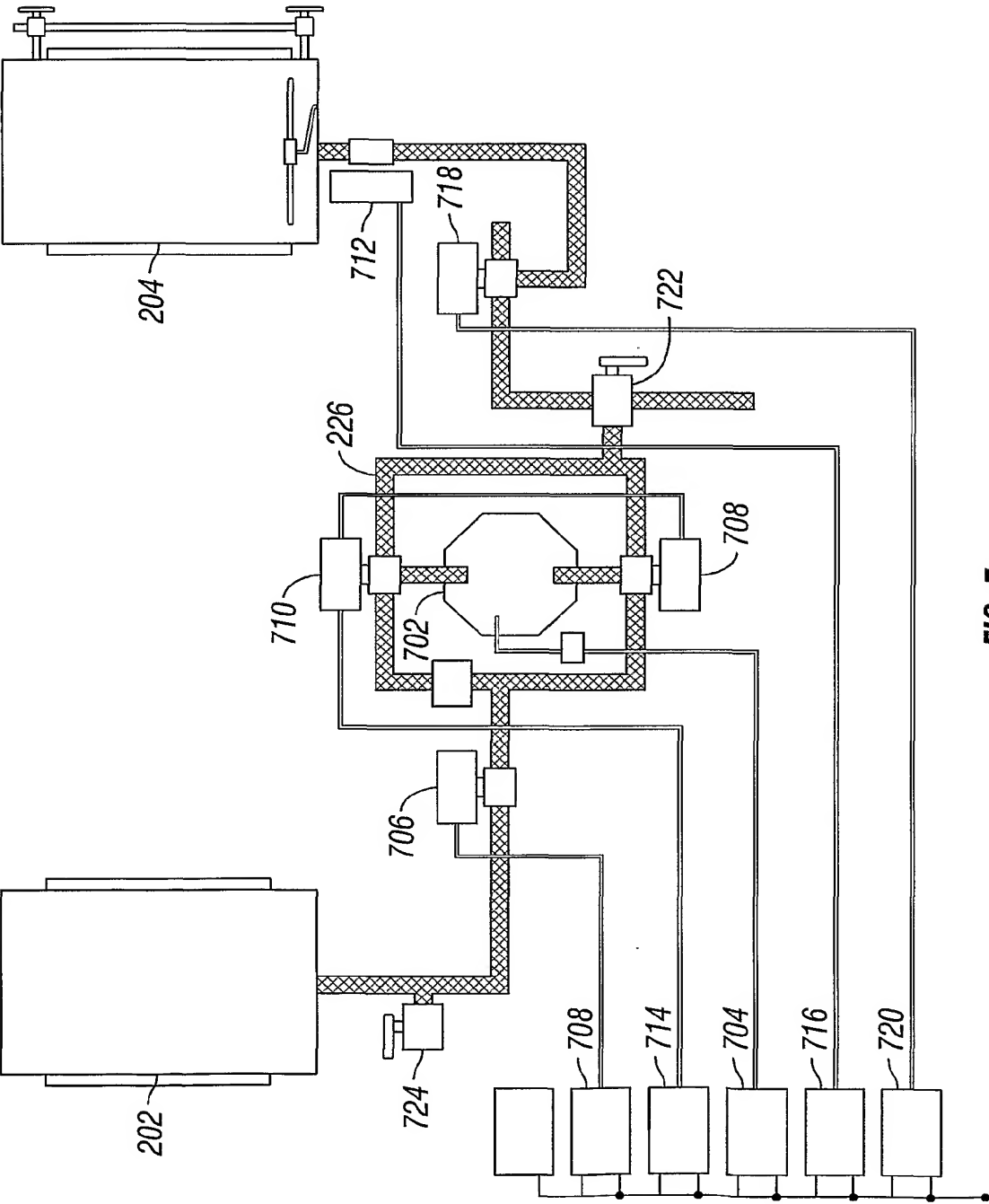


FIG. 7

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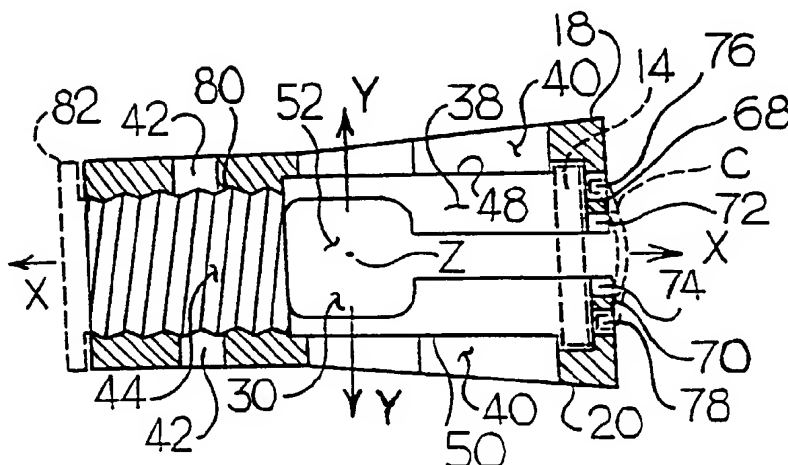
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(57) Abstract: A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae that includes a body and an engaging member. The body extends along a longitudinal axis having a first portion and two or more legs depending from the first portion. The legs are laterally spaced apart from each other and define a second end of the body spaced opposite the first end. The legs define an engaging member receiving cavity. An engaging member, such as a disc, is secured to the body and receiving within the engaging member receiving cavity, wherein the engaging member is secured to the body only by engagement of the engaging member with the legs. During installation, the engaging member causes the legs to flex.



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SPINAL IMPLANT DEVICE  
BACKGROUND OF THE INVENTION

1) Field of the Invention

5           The present invention relates to surgical procedures for stabilizing the spine, restoring disc height and reestablishing anatomic curves of the spine and, more particularly, to a spinal implant device for use in such procedures.

2) Description of the Prior Art

10           The human spinal column includes over twenty bones or vertebrae. Spinal disc cartilage is positioned between the adjacent vertebrae. Through the wear and tear of everyday living, damage can occur between the spinal disc cartilages positioned between the adjacent vertebrae  
15 or the vertebra itself. This degeneration can cause excessive back pain.

          A number of procedures and devices has been developed to correct this problem, such as interbody fusion devices. One of the most popular interbody fusion devices  
20 has taken on the form of a cylindrical implant, such as described in U.S. Patent Nos. 4,501,269; 4,743,256; 4,834,757; 4,878,915; 4,961,740; 5,015,247; 5,055,104; and 5,192,327. These cylindrical implants can either be threaded or pounded into the disc space between the  
25 adjacent vertebrae.

          In each of the above-identified patents, the cross section of the implant is constant throughout its length and is typically in the form of a right circular cylinder. An advantage of the circular design is that  
30 current surgical drills can easily drill a substantially circular profile into a bone. The bone is more difficult to prepare for other profiles.

          However, one problem encountered with these prior art devices is that they do not maintain or restore the  
35 normal anatomy of the fused spine segment. In other words, once the disc is removed, the normal lordotic or kyphotic curvature of the spine is eliminated.

          Several attempts have been made to provide implants that attempt to restore the curvature of the

spine. U.S. Patent Nos. 5,669,909 and 5,683,463 provide one-piece, frusto-conical shaped implants. Although in theory these implants may restore the curvature of the spine, they are difficult to install since special reamers  
5 may be needed to provide a tapered hole or a cylindrical hole must be modified by the implant which could put undue stress on the adjacent vertebrae.

U.S. Patent No. 5,653,763 describes a multi-piece rectangular-shaped dynamic implant that includes  
10 rectangular-shaped legs hinged at one end. An arrangement for separating the legs is provided that includes a shaft and a nut received within an interior space defined by the legs. This device requires special surgical tools to prepare a rectangular space between the adjacent vertebrae.  
15 Further, the hinged body may affect the integrity of the implant over time. Also, this device has no areas to receive bone mass to facilitate healing.

U.S. Patent No. 5,554,191 discloses an intersomatic vertebrae cage inserted from the posterior  
20 approach between two vertebra. This arrangement includes an integral body having two legs with a multi-piece adjustment mechanism to adjust the spacing between the legs. The cage is rectangular in cross section and has no areas defined to receive bone mass to facilitate healing.

25 Therefore, it is an object of the present invention to provide a spinal implant device that is relatively easy to install either posteriorly or anteriorly, maintains the appropriate curvature of the spine and facilitates healing.

30 SUMMARY OF THE INVENTION

The present invention is a dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae that includes a body and an engaging member secured to the body. The body can be made from  
35 either titanium, nitinol, stainless steel or other bio-compatible material. The body extends along a longitudinal axis having a first portion and two or more legs depending

from the first portion. The first portion has a first end with a width of a first lateral distance. Preferably, the first portion is substantially cylindrical in shape and the first portion can be hollow. The legs are laterally spaced  
5 apart from each other and define a second end of the body spaced opposite from the first end. The second end has a width of a second lateral distance. The legs define an engaging member receiving cavity. Preferably, the legs are spaced apart from each other and define a passageway  
10 through the body. The passageway extends along an axis transverse to the longitudinal axis. Preferably, the first portion and the legs have curved outer surfaces, each of the outer surfaces having the same radius of curvature. The engaging member is secured to the body and received  
15 within the engaging member receiving cavity, wherein the engaging member is secured to the body only by engagement of the engaging member with the legs. Preferably, the engaging member includes a threaded passageway for threadably receiving an adjustment rod for engaging the  
20 engaging member with the legs. Preferably, the engaging member is a disc.

The engaging member slidably contacts the body whereby when the engaging member is positioned at a first position, the second lateral distance can equal the first  
25 lateral distance, or be less than or greater than the first lateral distance, and when the engaging member is positioned at a second position, the engaging member causes the legs to flex and the second lateral distance is different from the first lateral distance. Preferably, at  
30 least one of the legs includes an inner surface that defines a ramp whereby movement of the engaging member along the longitudinal axis contacts the ramp causing the leg to flex in a lateral direction and varying the second lateral distance. Preferably, when the second engaging  
35 member is positioned at the second position, the second lateral distance is greater than the first lateral distance. Also, when the engaging member is positioned at



the second position, the engaging member is adjacent the second end.

The body can have an outer surface with a radial projection or more preferably, a plurality of radial projections extending therefrom such as in the form of threads. The threads can be positioned on either the first portion or the legs or both.

The first portion can also include an inner surface that defines a hollow cavity which is in communication with the engaging member receiving cavity. The hollow cavity can be open ended. An end cap can be provided to close off the open end of the passageway. The end cap can be made of polymeric material. Preferably, the first portion defines one or more passageways for permitting bone mass to grow therethrough.

The present invention is also a method for installing the above-described dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae that includes the steps of: forming a body receiving passageway between two adjacent vertebrae for receipt of a substantially cylindrical-shaped insert; inserting the body into the body receiving passageway; and securing the engaging member to the second end of the body causing the legs to flex so that the second lateral distance increases whereby the second lateral distance is greater than the first lateral distance and the engaging member is only held in place by the legs. The method can further include the steps of: placing bone tissue within the engaging member receiving cavity and a bone receiving cavity defined in the first portion of the body; securing an end cap to the first end of the body after the bone tissue has been placed within the first portion; and/or installing a second dynamic fusion device between the adjacent vertebrae which is adjacent to the installed fusion device.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a side elevational view of a fusion device of the prior art;

Fig. 2 is a plan view of a body of a spinal implant device made in accordance with the present invention;

Fig. 3 is a side elevational view of the body shown in Fig. 2;

Fig. 4 is a forward end view of the body shown in Fig. 2;

Fig. 5 is a rearward end view of the body shown in Fig. 2;

Fig. 6a is a sectional view taken along lines VIa-VIa of Fig. 5;

Fig. 6b is a partial, sectional view of a portion of a body of a spinal implant device shown in Fig. 2;

Fig. 7 is a plan view of the body shown in Fig. 2 having a disc received therein made in accordance with the present invention;

Fig. 8 shows a side elevational view of the body and disc shown in Fig. 7 with the disc in a second position;

Fig. 9 shows a plan view of the disc shown in Fig. 7;

Fig. 10 is a perspective view of the disc shown in Fig. 9;

Fig. 11 is a side elevational view of the body, wherein legs of the body diverge;

Fig. 12 is a side elevational view of the body shown in Fig. 2 with a disc received therein;

Fig. 13 is an elevational view of the disc shown in Fig. 12;

Fig. 14a is a top plan view of a plug used to install the spinal implant device made in accordance with the present invention;

Fig. 14b is a side elevational view of the plug shown in Fig. 14a;

Fig. 14c is an end elevational view of the plug shown in Fig. 14a;

Fig. 14d is an elevational view of the plug shown in Fig. 14a installed between two adjacent vertebrae;

5 Fig. 15 is a side elevational view of the spinal implant device shown in Fig. 2 having a disc positioned therein from the forward end of the body;

Fig. 16 is an end view of two spinal implants shown in Fig. 2 installed between two adjacent vertebrae;

10 Fig. 17 is a partial, sectional view of the spinal implant device shown in Fig. 12 installed between two adjacent vertebrae;

Fig. 18 is another embodiment of a spinal implant device similar to the body shown in Fig. 2 having a threaded outer surface;

Fig. 19 is an end view of the spinal implant device shown in Fig. 2 received within a cannula;

Fig. 20 is a rearward end view of another embodiment of a spinal implant device made in accordance with the present invention; and

Fig. 21 is a sectional view taken along lines XXI-XXI of Fig. 20.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 shows a prior art unitary spinal implant device 2 having a right cylindrical shape secured in a disc space between two adjacent vertebrae 4 and 6. This type of device affects the natural curvature of the spine.

30 Figs. 2-13 show a spinal implant device or dynamic fusion device 10 for facilitating arthrodesis in a disc space between adjacent vertebrae made in accordance with the present invention, which when implanted, restores the natural curvature of the spine. The spinal implant device 10 includes a body 12 and an engaging member or disc 14.

35 Referring specifically to Figs. 2 and 3, the body 12 extends along a longitudinal axis X and includes a first portion 16 having two legs 18 and 20 extending therefrom.

The body 12 includes a first end or forward end 22 and a second end or rearward end 24 positioned opposite the first end 22. The first end 22 has a width 26 which is a first lateral distance as shown in Fig. 4. The second end 24 has a width 28 which is a second lateral distance as shown in Fig. 5. The widths 26 and 28 can be equal to each other or width 28 can be greater than or less than width 26. Referring back to Fig. 3, the legs 18 and 20 define an engaging member receiving cavity or disc receiving cavity 30. Preferably, the body 12 is made of stainless steel, titanium, nitinol or any other bio-compatible material which will provide rigidity, but permit the legs 18 and 20 to flex.

As shown in Fig. 5, the legs 18 and 20 have curved outer surfaces 32 and 34, which have a radius of curvature that is less than, greater than or equal to the radius of the first portion 16 as shown in Fig. 4. The first portion 16 is substantially cylindrical in shape having flats 35 defined on opposite sides. Alternatively, the first portion 16 can be cylindrically shaped. As shown in Figs. 2, 3, 6a and 7, the legs 18 and 20 also define several passageways 36 and 38 that extend along axes Y and Z which are transverse to the longitudinal axis X. As shown in Figs. 6a and 7, passageway 38 is defined by holes 40 defined in legs 18 and 20. Also, a plurality of holes 42 is defined in the first portion 16 defining a passageway 44. A through-hole 51 is defined by an inner surface 48 of the first portion 16, which is in communication with the disc receiving cavity 30 and defines a bone receiving cavity 52. The passageways 36, 38 and 44 facilitate bone growth through the body both along axes Y and Z.

Referring to Figs. 5 and 6a, the legs 18 and 20 include two lips 68 and 70 that face each other. Each of the lips 68 and 70 includes arcuate inner surfaces 72 and 74, respectively, which define a portion of the disc receiving cavity 30. Each of the lips 68 and 70 includes holes 76 and 78 which are laterally spaced apart. Also, as

shown in Fig. 6a, the first portion 16 defines a threaded inner surface 80 that defines an open ended passageway, which is adapted to receive an end plug 82, shown in phantom, to close off the open ended passageway.

5               With reference to Figs. 9 and 10, the disc 14 is ring shaped and has an outer surface 46 and a threaded inner surface 47. The inner surface 47 may or may not be threaded. Preferably, the disc 14 is made of the same material as the body 12, although they can be made of  
10 different materials. Fig. 7 shows the disc 14 received within the disc receiving cavity 30 and positioned between the first end 22 and the second end 24. Preferably, as shown in Figs. 6a and 6b, inner surfaces 48 and 50 of the legs 18 and 20 are curved and/or inclined and have the same  
15 shape whereby a lateral distance A defined between the inner surfaces of the legs varies along the longitudinal axis X (see Fig. 6b). Preferably, the lateral distance A decreases along the longitudinal axis X moving toward the second end 24 and into recessed slots defined near the  
20 second end 24 prior to positioning the disc 14 within the disc receiving cavity 30. Hence, the disc 14 is moved toward the second end 24, the outer surface 46 of the disc 14 contacts the inner surfaces 48 and 50 of the legs 18 and 20, which are then flexed and forced apart in a lateral  
25 direction along the Y axis thereby moving the inner surfaces 48 and 50 at the second end 24 apart from a distance B to B' as shown in Figs. 6b and 8.

Fig. 11 shows the body 12 having legs 18' and 20' diverging in an outwardly direction as opposed to extending  
30 in a straight direction shown in Fig. 3. The body 12 can be formed in the arrangement shown in Fig. 11. A removable clip C, shown in phantom in Figs. 5 and 6a, can be provided and received in holes 76 and 78 to cause the legs 18' and 20' to look like legs 18 and 20. The clip C can then be  
35 removed during installation with the aid of calipers or tweezers. The clip C is shown installed externally of the

body 12. Clip C can also be positioned within the interior of the body 12.

Figs. 12 and 13 show an alternate disc 14'. Disc 14' includes two circular portions 62 and 64 and a tapered threaded portion 66. As shown in Fig. 12, the threaded portion 66 initially engages with arcuate inner surfaces 72 and 74. Rotation of disc 14' in a clockwise direction about the longitudinal axis X causes the disc 14' to move toward the first end 22 until the circular portion 64 contacts the inner surfaces 72 and 74 at which point the inner surfaces 72 and 74 are sandwiched between the circular portion 62 and the threaded portion 66.

Installation of the spinal implant device 10 is described below. In a posterior installation, initially the spinal disc area between two adjacent vertebrae is identified. The diseased spinal disc is removed.

As shown in Figs. 14a-14c, two plastic plugs P are then to be inserted into the disc space defined between the adjacent vertebrae. Plugs P are tapered having a first end f having a circular shape and a second end g having semi-circular shaped ends and straight sides, wherein the length of g is greater than the length of f. The thickness of the plug is T and the plug has a varying width W. The thickness of the plug T is equal to the diameter of the circle defined at the first end f.

A surgeon installing the spinal implant device 10 must determine the appropriately sized plug, namely, the minimum and maximum width W and the thickness T of the plug P. Initially, a first plug P is inserted flat into the disc space on its side, as shown in Fig. 14b, so that second end g faces anteriorly in the patient and the plug P is inserted in the disc space. The plug P is then rotated 90° about the longitudinal axis X' as shown in Figs. 14a, 14c and 14d to distract the vertebrae bones anteriorly and restore the lordotic curve to the spine. This same procedure is performed on the other side of the spine. The reason for inserting the plug P is to stretch the ligaments

of the spine, which makes it easier to deploy the spinal implant device 10 when it is placed in the disc space.

Next, one of the plugs P is removed and the site is prepared by reaming out a hole (defined by the two adjacent vertebrae) having a diameter approximately equal to the width 26 of the first portion 16 for receipt of a spinal implant device 10. This reaming procedure will remove a small portion of the end plates of each vertebrae. The body 12, such as shown in Figs. 2 and 3, is inserted into the hole. Preferably, the width W' of the second portion 18 is approximately equal to the width of the first portion 16. Initially, the second end 24 of the body 12 is forced into the implant receiving recess followed by the first end 22. At this point, the spinal implant device 10 has a substantially cylindrical profile, which means a cylindrical profile except for the flats 35. Alternatively, the profile can be completely cylindrical. Threaded inner surface 47 threadably receives a threaded end of a rod or plunger 98 as shown in Fig. 15. The direction of the threads defined on the threaded inner surface 47 is opposite from the direction of the threads defined on the outer surface 46. The plunger 98 is rotated about the longitudinal axis X threadably engaging with the threaded inner surface 47 of the disc 14. The disc 14 and the plunger 98 are moved in a first direction so that the disc 14 moves along the longitudinal axis X adjacent the surface 80. Then, the disc 14 is forced toward the second end 24 with the aid of the rod or plunger 98, which passes through the longitudinally extending passageway 44 that communicates with the disc receiving cavity 30 as shown in Fig. 15. This action forces and flexes the legs 18 and 20 in a lateral direction along the Y axis which, in turn, causes the adjacent vertebral bodies to move in the lateral direction, thereby causing a proper curvature of the spine. The disc 14 comes to rest adjacent to lips 68 and 70 as shown in Fig. 8 and in phantom in Fig. 6a. The plunger 98 is then rotated in a second direction about the

longitudinal axis X and disengaged from the disc 14 and removed away from the passageway 44 resulting in an installed spinal implant device 10 as shown in Fig. 8.

5 The other plug P, which is now positioned adjacent to the installed spinal implant device 10, is removed and a second spinal device 10 is installed in a similar manner as described resulting in the spinal implant arrangement between two adjacent vertebrae 4 and 6 as shown in Fig. 16. The through-hole 51 and disc receiving cavity 10 30 define a bone receiving cavity 52. The bone receiving cavities 52 of both of the installed implant devices can then be packed with bone tissue. It is preferable to provide as much bone tissue in the bone receiving cavity 52. This can be accomplished by tamping the bone tissue in 15 the bone receiving cavity 52. The passageways 36, 38 and 44 permit the harvested bone tissue to grow therethrough and fuse the adjacent vertebrae via arthrodesis. An optional plug 82 having a threaded end or snaps, which is preferably made from polyurethane or other non-metallic or 20 metallic material, can be threaded or snapped into the first end 22. The threaded end of the plug 82 engages with the threaded inner surface 80 to plug through-hole 51 and prevent the bone mass from falling out of the body 12. Finally, the patient is sutured and the procedure is 25 complete.

Installation of the spinal implant device 10 for anterior installation is described below. Initially, the disc area between two adjacent vertebrae is identified. The diseased spinal disc is removed. Plugs P are inserted 30 and rotated to stretch the spinal ligaments as previously described. One plug P is then removed. A reamer reams out portions of adjacent vertebrae on one side of the spinal column forming a spinal implant receiving area. The threaded end plug 82 is first received by the threaded 35 inner surface 80. The first end 22 of the body 12 is then placed in the spinal implant receiving area and the second end 24 is tapped by a mallet into the spinal implant



receiving area until the body 12 is positioned between the two adjacent vertebrae. A second area is reamed between the two adjacent vertebrae on an opposite side of the spinal column forming a second spinal implant receiving area. The second body 12 is placed in the second spinal implant receiving area with the first end 22 preceding the second end 24. Bone tissue is placed within the bone receiving cavities 52 of both bodies. Then, discs 14' are engaged with lips 68 and 70 by rotating or screwing a respective disc 14' about the longitudinal axis X in a first direction until the circular portion 62 abuts against lips 68 and 70 and the surfaces 72 and 74 rest on circular portion 64 as shown in Fig. 12. Alternatively, disc 14' can be pushed toward the first end 22 of the body 12 until the circular portion 62 abuts the legs 68 and 70. Finally, the patient is sutured and the procedure is complete.

Fig. 18 shows another embodiment of a spinal implant device 90 made in accordance with the present invention. Specifically, the spinal implant device 90 includes a body 92 similar to the body 12, except an outer surface 94 of the body 92 is threaded. The threads extend from the first portion 16 to the legs 18 and 20 (not shown). All other aspects of the body 92 are the same as the body 12. The threaded body 92 provides radial projections to prevent the installed body 92 from dislodging. Radial projections or threads can be provided on the first portion 16 or either legs 18 and 20. The above-described installation procedure will further require threading the body 92 into the disc receiving areas as opposed to press fitting into place.

With reference to Fig. 11, the body 12 can be provided with diverging legs 18 and 20. This arrangement can be inserted into the disc space through a cannula 96 as shown in Fig. 19 or clamps C can be provided. The clamps C are then removed prior to insertion of the disc 14 or 14' through the use of pliers, tweezers or the like.

Nitinol can be used for either body 12 or 92

whereby in one state the overall profile of the body is cylindrical as shown in Fig. 4 and after heat is applied from the human body, the legs 18 and 20 take on a tapered shape as shown in Fig. 11. The heat from the patient's body would be applied after the body 12 or 92 is received in the respective disc receiving area. Also, although only two legs 18 and 20 are shown, any number of legs can be provided to define the disc receiving cavity.

The present invention overcomes the deficiencies of the prior art cylindrical spinal implants and is easier to install than tapered implants. Further, the present invention provides a dynamic spinal implant through a one-piece body, which provides improved integrity over a multi-piece body and minimizes the number of mechanical components needed. Further, the present invention can be inserted posteriorly or anteriorly and can receive bone mass to facilitate healing.

Also, the present invention can be used at any location of the spine. Furthermore, since the present invention uses the same body 12 for anterior and posterior procedures, then the number of inventory parts required is minimized to one body 12, two discs 14 and 14' and an end cap 82 to perform either an anterior or posterior procedure. This will reduce the cost to manufacture the present invention.

Finally, another embodiment of the present invention is a spinal implant device 10'' that includes one rectangular shaped wide body 12'' and a rectangular engaging member 14'' that can be used in lieu of two bodies 12. The spinal implant device 10'' is shown in Figs. 20 and 21.

Having described the presently preferred embodiments of the invention, it is to be understood that it may otherwise be embodied within the scope of the appended claims.

I Claim:

1. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae, comprising:

5 a body extending along a longitudinal axis having a first portion and two or more legs depending from said first portion, said first portion having a first end having a width of a first lateral distance, said legs laterally spaced apart from each other and defining a second end of said body spaced opposite from said first end, said second  
10 end having a width of a second lateral distance, said legs defining an engaging member receiving cavity; and

an engaging member secured to said body and received within said engaging member receiving cavity, wherein said engaging member is secured to said body only  
15 by engagement of said engaging member with said legs.

2. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said engaging member slidably contacts said body whereby when said engaging member is  
5 positioned at a first position the second lateral distance approximately equals the first lateral distance and when the engaging member is positioned at a second position said engaging member causes said legs to flex and the second lateral distance is different than the first lateral  
10 distance.

3. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein when said engaging member is positioned at the second position the second lateral  
5 distance is greater than the first lateral distance.

4. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 2, wherein said engaging member positioned at the second position is adjacent said second end.

5. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said first portion is substantially cylindrical in shape.

6. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 5, wherein said first portion is hollow.

7. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said legs are spaced apart from each other defining a passageway through said body.

8. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 7, wherein said legs define a passageway extending along an axis transverse to the longitudinal  
5 axis.

9. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said first portion and said legs have curved outer surfaces, each of said outer  
5 surfaces having the same radius of curvature.

10. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said body has an outer surface having a radial projection.

11. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 10, wherein said body outer surface comprises a plurality of radial projections in the form of  
5 threads.

12. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebra as claimed in claim 11, wherein said threads are defined on said first portion.

13. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said first portion includes an inner surface that defines a hollow cavity that is in  
5 communication with the engaging member receiving cavity.

14. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, further comprising an end cap, said first portion includes an inner surface defining a  
5 passageway having an open end, wherein said end cap attaches to said first end of said first portion and closes off the open end of the passageway.

15. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said body is selected from the group consisting of titanium, nitinol and stainless steel.

16. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said first portion is substantially cylindrical in shape and includes an inner  
5 surface that defines a hollow cavity that is in communication with the engaging member receiving cavity, said first leg and said second leg defining a passageway

extending along an axis transverse to the longitudinal axis for bone mass to grow therethrough.

17. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 16, wherein said body has an outer surface that includes a radial projection.

18. A method for installing a dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae, said method comprising the steps of:

5 providing a body extending along a longitudinal axis having a first portion and two legs depending from said first portion, said first portion having a first end having a width of a first lateral distance, said legs laterally spaced apart from each other and defining a second end of said body spaced opposite from said first  
10 end, said second end having a width of a second lateral distance, said legs defining an engaging member receiving cavity, and

an engaging member adapted to be secured to said body and received within said engaging member receiving  
15 cavity;

forming a body receiving passageway between two adjacent vertebrae for receipt of said body;

inserting said body into said body receiving passageway; and

20 securing said engaging member to said second end of said body causing said legs to flex so that the second lateral distance increases whereby the second lateral distance is greater than the first lateral distance and the engaging member is only held in place by said legs.

19. A method as claimed claim 18, further comprising the step of placing bone tissue within the engaging member receiving cavity and a bone receiving cavity defined in said first portion of said body.

20. A method as claimed in claim 19, further comprising the step of securing an end cap to said first end of said body after bone tissue has been placed within said first portion.

21. A method as claimed in claim 18, further comprising the step of installing a second dynamic fusion device between the adjacent vertebrae which is adjacent to the installed fusion device.

22. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said engaging member is secured to said second end of said body by moving said engaging member from a position external of said body to engage with said second end of said body.

23. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein at least one of said legs includes an inner surface that defines a ramp, whereby movement of said engaging member along the longitudinal axis contacts said ramp causing said leg to flex in a lateral direction and varying the second lateral distance.

24. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 14, wherein said end cap is made of a polymeric material.

25. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said first portion defines one or more passageways for permitting bone mass to grow therethrough.

26. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, where said engaging member includes a threaded passageway for threadably receiving an adjustment  
5 rod for engaging said engaging member with said legs.

27. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 1, wherein said engaging member is a disc.

28. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 10, wherein said radial projection extends from at least one of said legs.

29. A dynamic fusion device for facilitating arthrodesis in a disc space between adjacent vertebrae as claimed in claim 11, wherein said threads are defined on said legs.



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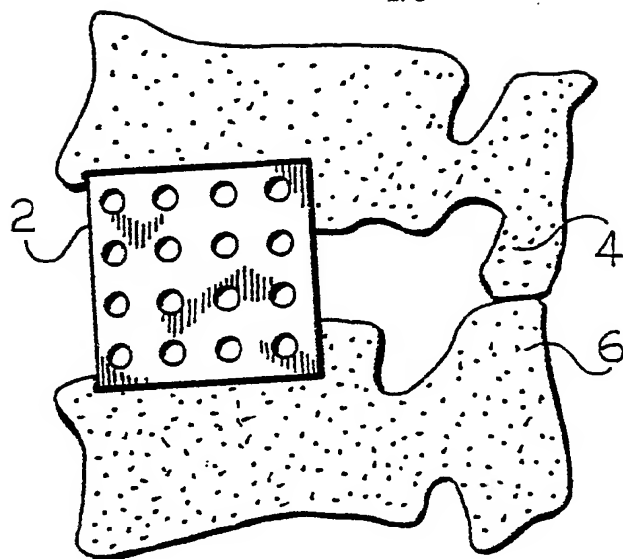


FIG. 1  
PRIOR ART

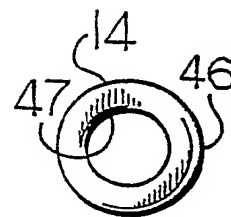


FIG. 9

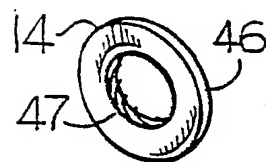


FIG. 10

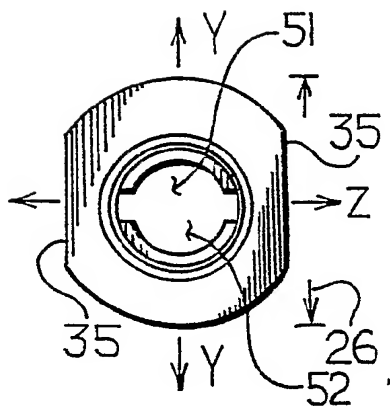


FIG. 4

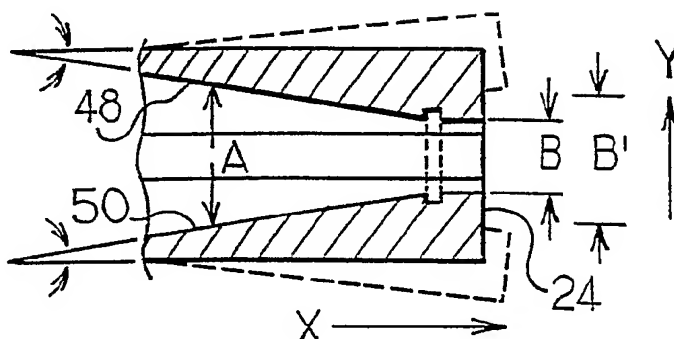


FIG. 6b

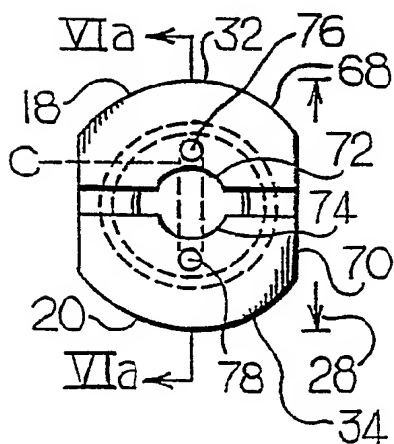


FIG. 5

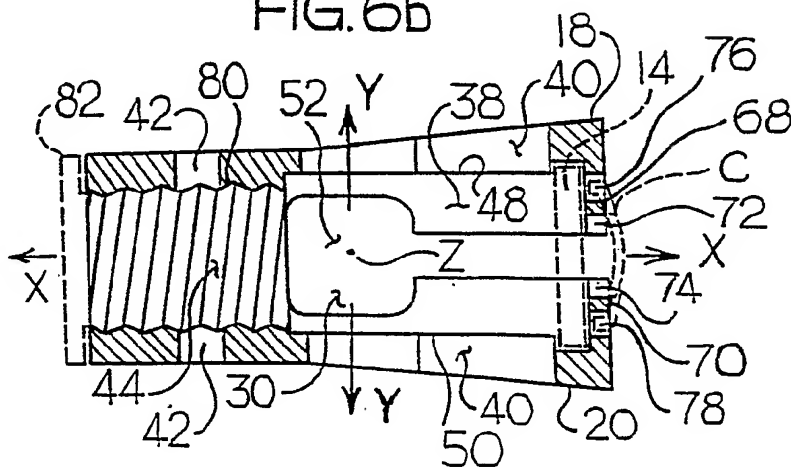
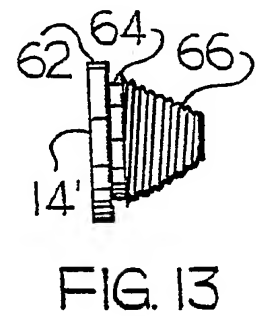
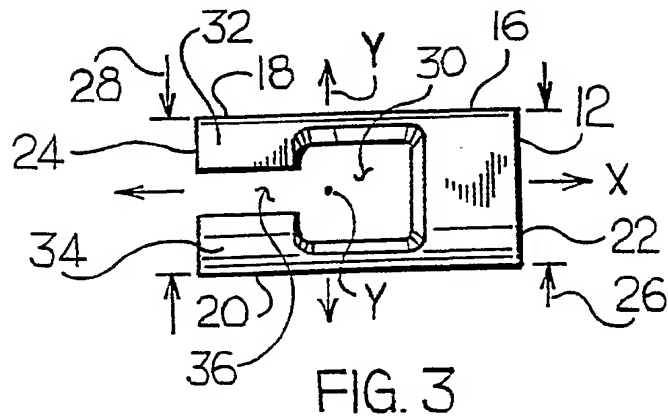
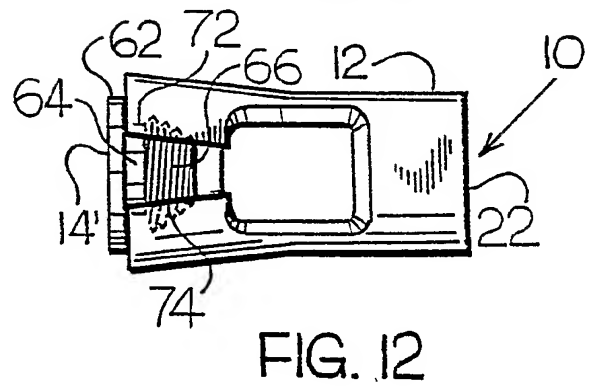
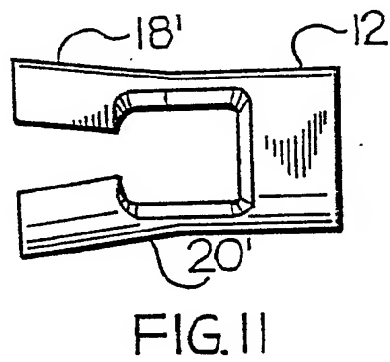
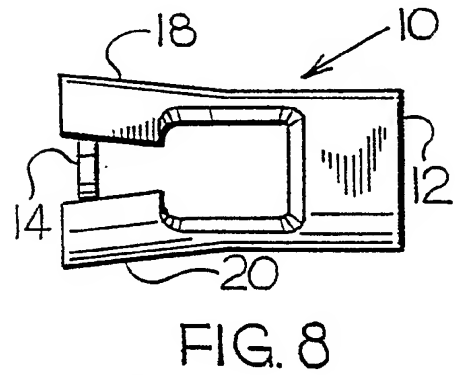
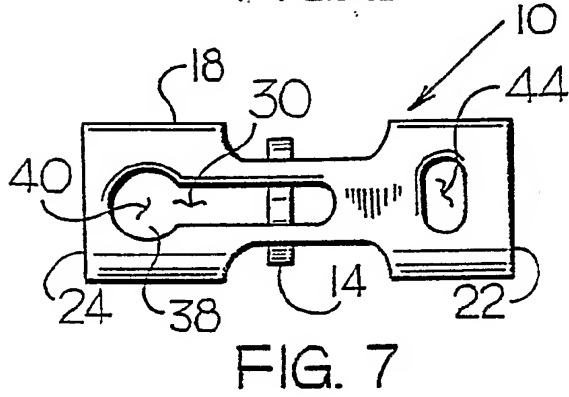
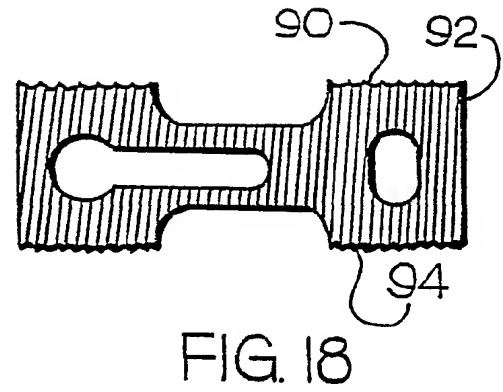
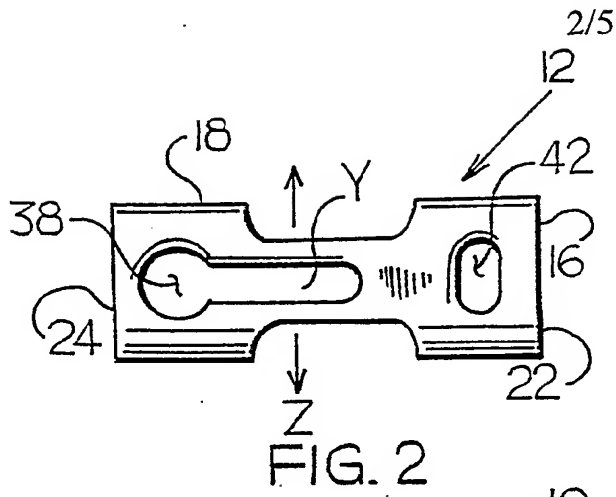


FIG. 6a



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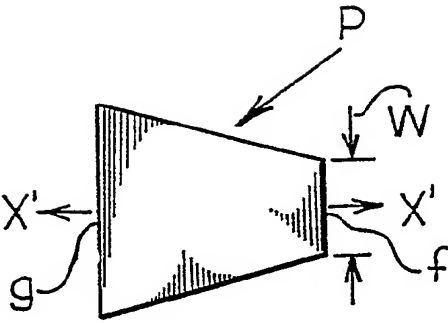


FIG. 14a

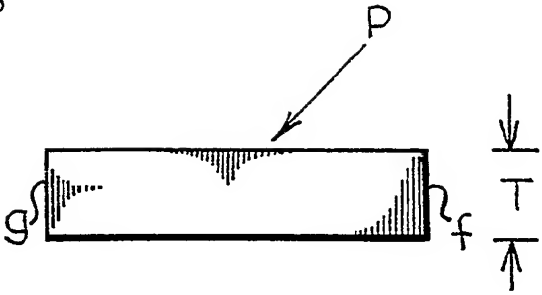


FIG. 14b

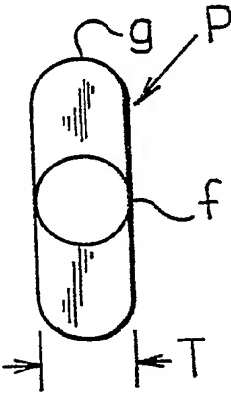


FIG. 14c

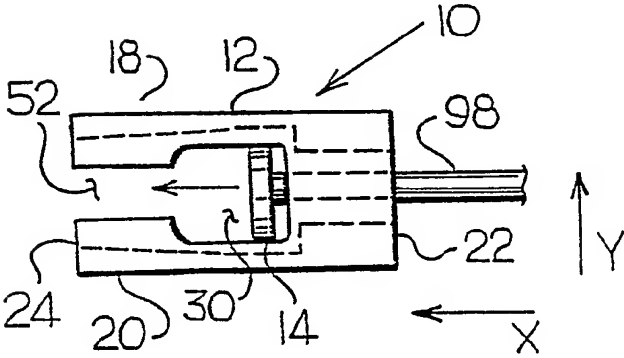


FIG. 15

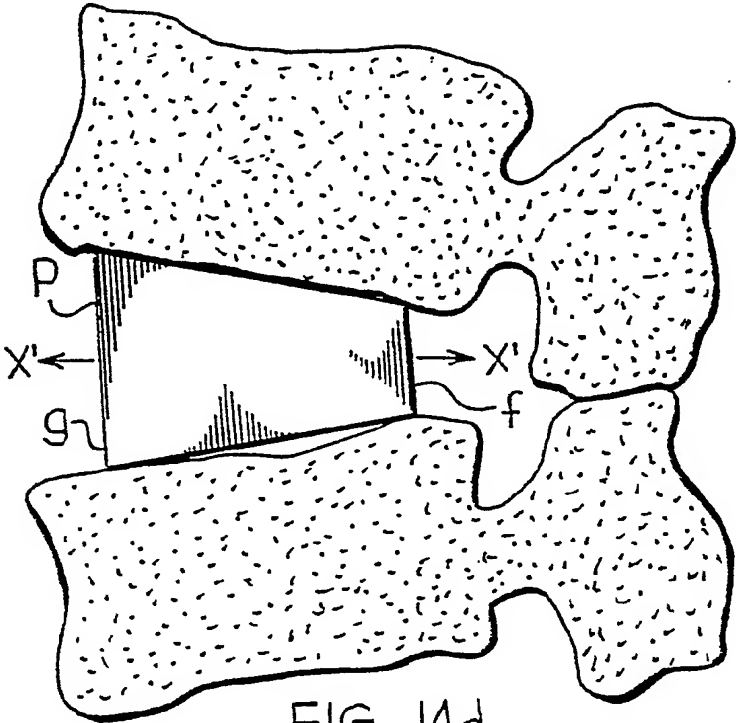


FIG. 14d

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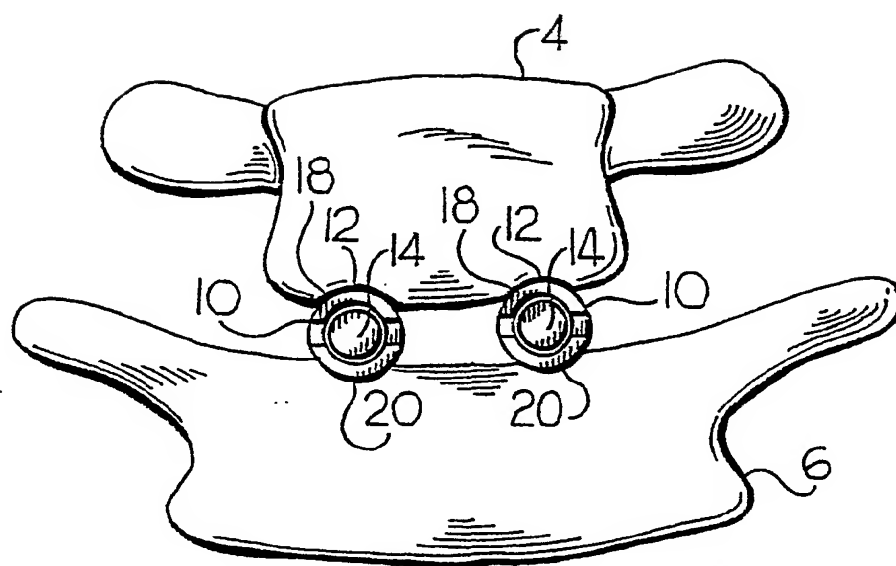


FIG. 16

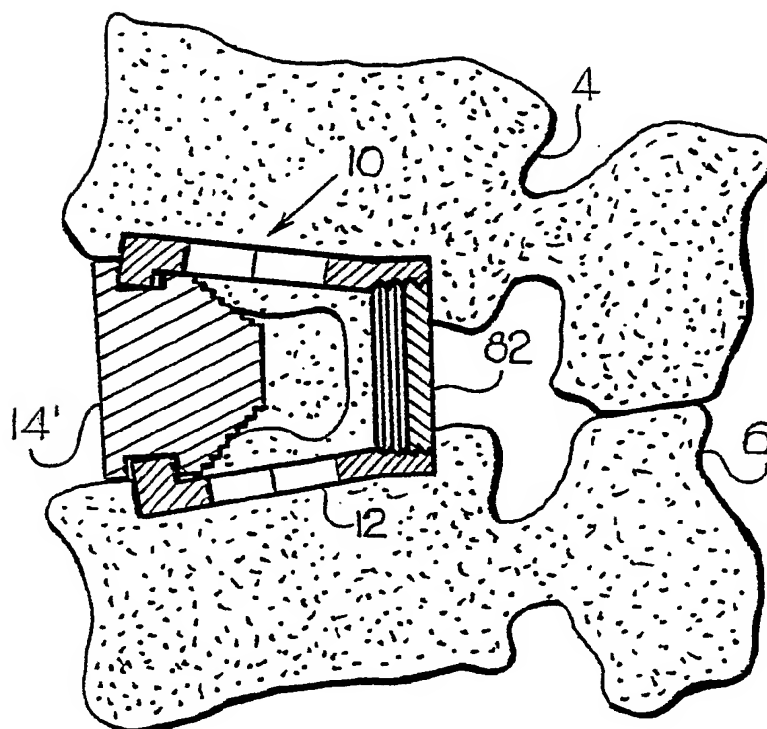


FIG. 17

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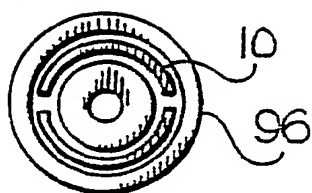


FIG. 19

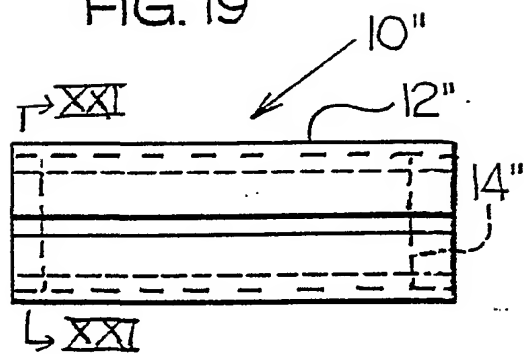


FIG. 20

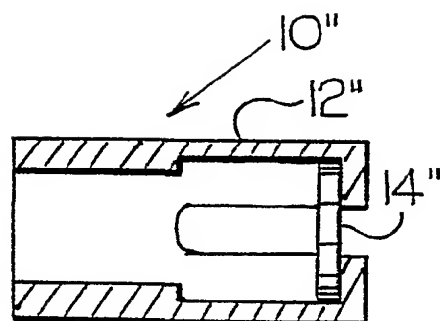


FIG. 21

## INTERNATIONAL SEARCH REPORT

 International application No.  
 PCT/US00/24568
**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61F 2/44, 2/30; A61B 17/00

US CL : 623/17.11, 18.11, 17.16, 908; 606/61

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.11, 18.11, 17.16, 908; 606/61, 60, 63, 73

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.             |
|-----------|---|-----------------------------------|
| A         | US 5,554,191 A (LAHILLE et al) 10 September 1996, col. 4, lines 49-51; col. 6, lines 32-48, 63-65; col. 8, lines 5-12; col. 10, lines 1-4, 44-46; col. 7, lines 27-41; col. 9, lines 21-32; Figures 6-8 and 15. | 1-4, 6-8, 10-15, 18, 21-26, 28-29 |
| A         | US 5,683,463 A (GODEFROY et al) 04 November 1997, col. 3, lines 23-25; col. 4, lines 23-25.   | 5, 9, 16-17                       |
| A         | US 5,593,409 A (MICHELSON et al) 14 January 1997, col. 2, lines 51-54; col. 10, lines 5-39.   | 14, 19-20, 24                     |
| A         | US 5,653,763 A (ERRICO et al) 05 August 1997, Abstract; col. 2, lines 63-67; col. 3, lines 15-33; col. 5, line 50 - col. 6, line 12; Figure 3.  | 18, 27                            |



Further documents are listed in the continuation of Box C.



See patent family annex.

\*

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Date of the actual completion of the international search

18 OCTOBER 2000

Date of mailing of the international search report

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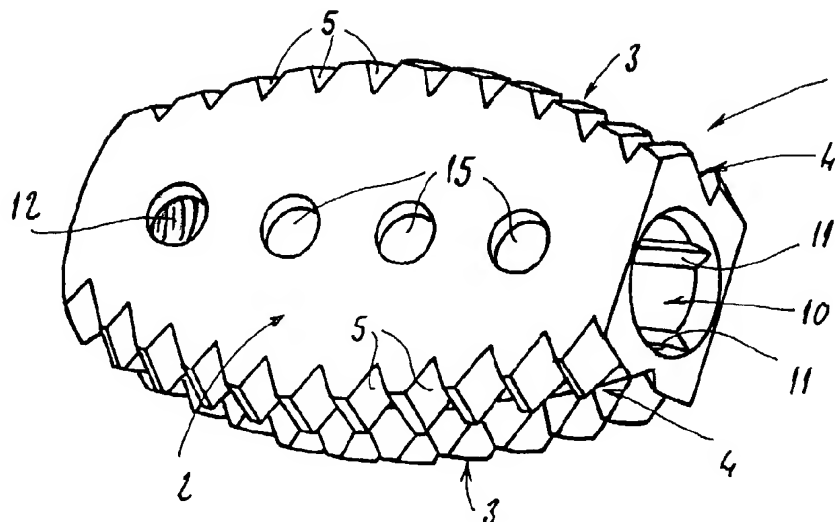
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DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM,  
HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK,  
LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX,  
MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI,

[Suite sur la page suivante]

(54) Title: INTERVERTEBRAL CAGE AND INSTRUMENT FOR SETTING SAME BETWEEN TWO VERTEBRAE

(54) Titre : CAGE INTERVERTEBRALE ET INSTRUMENT DE MISE EN PLACE DE CETTE CAGE ENTRE DEUX VERTEBRES



(57) Abstract: The invention concerns a cage (1) having an elongated shape and delimiting four lateral surfaces (2, 3), two main surfaces (4) defining between them the thickness of the cage, and two secondary surfaces (5) designed to be urged in contact with the vertebrae (50); said secondary surfaces (3) have a convex curvature matching the concave shape of the vertebral end-plates (51) in the antero-posterior plane, and the thickness of the cage (1) is reduced, that is can range between 3.5 and 7 mm. The invention is characterised in that the cage has, at least at one of said secondary surfaces (3), a longitudinal groove (4) arranged in the median zone of said secondary surface (3), and it has a curved shape at that same surface, viewed in the longitudinal direction of the cage (1).

[Suite sur la page suivante]



WO 02/38086 A1



SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

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**(84) États désignés (régional) :** brevet ARIPO (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), brevet eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), brevet européen (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

*En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.*

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**(57) Abrégé :** La cage (1) présente une forme allongée et délimite quatre faces latérales (2, 3), à savoir deux faces principales (2) définissant entre elles l'épaisseur de la cage, et deux faces secondaires (3) destinées à venir en contact avec les vertèbres (50); lesdites faces secondaires (3) présentent, une courbure de forme convexe correspondant à la forme concave que présentent les plateaux vertébraux (51) dans le plan antéro-postérieur, et l'épaisseur de la cage (1) est réduite, c'est-à-dire peut aller de 3, 5 à 7 mm. Selon l'invention, la cage présente, au niveau d'au moins une desdites faces secondaires (3), une rainure longitudinale (4) aménagée dans la zone médiane de cette face secondaire (3), et en ce qu'elle a une forme courbe au niveau de cette même face, vue dans la direction longitudinale de la cage (1).



## **CAGE INTERVERTEBRALE ET INSTRUMENT DE MISE EN PLACE DE CETTE CAGE ENTRE DEUX VERTEBRES**

La présente invention concerne une cage intervertébrale et un instrument de mise en place de cette cage entre deux vertèbres.

5 Une cage de ce type est utilisée pour rétablir la distance anatomique de deux vertèbres lorsque le disque reliant ces vertèbres est affaissé, et pour opérer une immobilisation relative de ces vertèbres par croissance osseuse dans l'espace intervertébral.

10 Pour la mise en place d'une telle cage, un logement approprié est aménagé au travers du disque et dans les plateaux vertébraux, les vertèbres sont distractées puis la cage est insérée dans le logement au moyen d'un instrument de mise en place et d'impaction.

Les cages existantes présentent généralement des formes cylindriques, tronconiques ou parallélépipédiques. Elles ont des dimensions  
15 relativement importantes dans le sens de leur épaisseur afin de délimiter des surfaces de contact relativement étendues avec les vertèbres. Ces surfaces ont pour but de prévenir au maximum le risque d'insertion des cages dans les vertèbres, résultant des sollicitations importantes et répétées que les vertèbres exercent sur elles. Les logements de réception  
20 de ces cages doivent eux-mêmes avoir des dimensions relativement importantes, de sorte que leur aménagement implique une ablation d'os conséquente, plutôt délicate à réaliser compte tenu de la proximité de la moelle épinière et des terminaisons nerveuses.

En outre, certaines cages d'épaisseur relativement importante  
25 occupent un espace non négligeable et conduisent par conséquent à un risque que la fusion des vertèbres ne soit pas parfaitement solide.

Les documents n° WO 95/08306 ou US 6 080 158 décrivent chacun une cage présentant une forme allongée et délimitant quatre faces latérales, à savoir deux faces latérales principales, placées parallèlement à  
30 l'axe de la colonne vertébrale lorsque la cage est mise en place et définissant entre elles l'épaisseur de la cage, et deux faces latérales secondaires, reliant les deux faces principales l'une à l'autre et destinées à venir en contact avec les vertèbres ; lesdites faces secondaires présentent, vues selon une direction perpendiculaire auxdites faces principales, une  
35 courbure de forme convexe correspondant à la forme concave que présentent les plateaux vertébraux dans le plan antéro-postérieur, et l'épaisseur de la cage est réduite, c'est-à-dire peut aller de 3,5 à 7 mm.

## 2

Les cages selon la technique antérieure ont pour inconvénients de présenter des risques de basculement non négligeables, particulièrement lorsqu'elles présentent des épaisseurs réduites, ainsi que des risques d'insertion douloureuse dans les vertèbres sous l'effet de la charge qui leur est transmise.

La présente invention vise à remédier à ces inconvénients essentiels.

Son but de fournir une cage intervertébrale peu invasive, c'est-à-dire limitant les opérations à accomplir pour l'aménagement du logement de réception de cette cage, présentant un risque limité d'insertion dans les plateaux vertébraux et garantissant l'obtention d'une fusion parfaitement solide des vertèbres.

La cage concernée est du type de celle connue par les documents antérieurs précités n° WO 95/08306 ou US 6 080 158.

Selon l'invention, la cage présente, au niveau d'au moins une desdites faces secondaires, une rainure longitudinale aménagée dans la zone médiane de cette face secondaire, et a une forme courbe au niveau de cette même face, vue dans la direction longitudinale de la cage.

Cette rainure et cette forme courbe permettent d'aménager deux zones d'appui décalées latéralement, qui favorisent la stabilité de la cage contre un risque de basculement. De plus, la rainure permet d'aménager un espace longitudinal pouvant recevoir des copeaux d'os ou pouvant être envahi par des cellules osseuses lors de leur croissance, ce qui permet de constituer une nervure osseuse apte à parfaitement caler la cage par rapport aux vertèbres. En outre, la courbure desdites faces secondaires augmente la surface de ces faces et supprime l'existence d'un angle saillant entre ces faces secondaires et les faces principales de la cage, ce qui favorise un appui non agressif de la cage contre les plateaux vertébraux et réduit ainsi le risque d'insertion douloureuse de la cage dans les vertèbres.

De préférence, la cage présente la rainure et la forme courbe précitées au niveau de ses deux faces secondaires.

Avantageusement, la cage présente au moins une série d'entailles au niveau d'au moins une de ses faces secondaires, ces entailles étant conformées pour délimiter des dents favorisant une légère insertion de la cage dans les plateaux vertébraux.

## 3

Cette légère insertion contribue à favoriser le maintien de la cage en position par rapport aux vertèbres le temps que s'opère la croissance des cellules osseuses.

Dans le même but, au moins une des parois principales et/ou  
5 secondaires de la cage peut comprendre au moins un trou destiné à être envahi par les cellules osseuses lors de leur croissance.

Avantageusement, la cage est percée longitudinalement d'un trou qui débouche dans l'une de ses faces d'extrémité, et comprend des cannelures aménagées dans la paroi qui délimite ce trou.

10 Ce trou et ces cannelures sont destinés à recevoir l'extrémité de forme correspondante de l'instrument de mise en place de la cage. La profondeur de ce trou et la présence de ces cannelures permettent une parfaite immobilisation de la cage par rapport à l'instrument de mise en place afin de permettre un positionnement fiable de la cage par rapport au  
15 logement de réception lors de l'insertion et de l'impaction de cette cage dans ce logement.

Selon une forme de réalisation préférée de l'invention, la cage présente un alésage taraudé dans le fond dudit trou, coaxial à ce trou.

Cet alésage est destiné à recevoir l'extrémité fileté d'une tige  
20 que comprend ledit instrument de mise en place, cette tige permettant une extraction de la cage si nécessaire. Il est ainsi rendu possible de tester l'implantation de la cage afin de vérifier si le logement de réception est correctement aménagé.

En conséquence de ce qui précède, l'instrument de mise en  
25 place de la cage comprend deux pièces, à savoir :

- une pièce tubulaire, dont une extrémité comprend une forme correspondant à celle dudit trou et desdites cannelures, et
- une tige engagée et pouvant coulisser dans cette pièce tubulaire, dont une extrémité comprend un filetage permettant son  
30 engagement dans ledit alésage taraudé.

Pour sa bonne compréhension, l'invention est à nouveau décrite ci-dessous en référence au dessin schématique annexé représentant, à titre d'exemple non limitatif, une forme de réalisation préférée de la cage intervertébrale et de l'instrument de mise en place de cette cage, qu'elle  
35 concerne.

La figure 1 est une vue en perspective de la cage ;

## 4

la figure 2 en est une vue de côté ;

la figure 3 en est une vue en bout ;

les figures 4 et 5 en sont des vues après mise en place entre deux vertèbres, respectivement latéralement et du côté dorsal, et

5 la figure 6 est une vue de côté de l'instrument.

Les figures 1 à 3 représentent sous différents angles une cage intervertébrale 1, destinée, ainsi que le montrent les figures 4 et 5, à rétablir la distance anatomique de deux vertèbres 50 lorsque le disque reliant ces vertèbres 50 est affaissé, et pour opérer une immobilisation  
10 relative de ces vertèbres 50 par croissance osseuse dans l'espace intervertébral.

La cage 1 présente une forme allongée et délimite quatre faces latérales 2, 3, à savoir deux faces latérales principales 2 et deux faces latérales secondaires 3.

15 Les faces 2 sont planes et destinées à être placées parallèlement à l'axe de la colonne vertébrale lorsque la cage 1 est mise en place. Elles définissent entre elles l'épaisseur de la cage 1, qui est relativement réduite, à savoir qui correspond à environ le quart de la longueur de la cage 1. En particulier, la cage 1 peut avoir une longueur de  
20 20 mm et donc une épaisseur de l'ordre de 5 mm.

Les faces 3 relient les faces 2 l'une à l'autre et sont destinées à venir en contact avec les vertèbres 50. Comme le montre la figure 4, ces faces 3 présentent, lorsqu'elles sont vues selon une direction perpendiculaire aux faces 2, une courbure de forme convexe correspondant  
25 à la forme concave que présentent les plateaux vertébraux 51 dans le plan antéro-postérieur. Ces faces 3, lorsqu'elles sont vues dans la direction longitudinale de la cage (cf. figure 3) ont de plus une forme courbe, et la cage 1 comprend deux rainures longitudinales 4, à section en forme de "V", qui débouchent dans la zone médiane de chacune d'elles.

30 La cage 1 présente quatre séries d'entailles 5 aménagées dans ses parois délimitées par les faces 3. Ces entailles 5 ont une forme de "V" à angle de 45°, et sont conformées pour délimiter des dents émoussées favorisant une légère insertion de la cage 1 dans les plateaux 51.

La cage 1 est en outre percée longitudinalement d'un trou 10  
35 qui débouche dans la face proximale d'extrémité. Elle comprend quatre cannelures proximales 11 aménagées dans la paroi qui délimite ce trou 10,

ces cannelures définissant les angles d'un carré comme le montre la figure 3. Les cannelures 11 permettent le calage de la cage 1 sur l'extrémité de l'instrument de pose comme cela apparaîtra plus loin. La cage comprend également un alésage taraudé 12 dans le fond du trou 10, coaxial à ce

5 dernier.

La cage 1 présente en outre des trous 15 traversant ses parois latérales 2, 3 et mettant le trou 10 en communication avec l'extérieur.

Les dimensions de la cage 1 autres que celles indiquées plus haut peuvent en particulier être les suivantes : hauteur : 9, 11 ou 13 mm  
10 (trois modèles étant prévus pour adapter la hauteur de la cage aux différentes hauteurs d'espace intervertébral possibles), diamètre générant la courbure des faces 3 dans le sens transversal de la cage : 12,91 mm, diamètre du trou 10 : 3,5 mm, diamètre des trous 15 : 2 mm.

L'instrument 20 de mise en place de la cage 1 comprend quant  
15 à lui deux pièces 25, 26, à savoir :

- une pièce tubulaire 25, dont une extrémité présente une zone de forme carrée 27 dont la forme correspond à l'espace carré délimité par les cannelures 11, et

- une tige 26 engagée et pouvant coulisser dans cette pièce  
20 tubulaire 25, dont une extrémité 28 comprend un filetage permettant son engagement dans l'alésage taraudé 12.

En pratique, deux cages 1 sont la plupart du temps mises en place au niveau d'un même disque intervertébral, de part et d'autre de la colonne vertébrale. Pour ce faire, comme cela se déduit de la figure 5, deux  
25 logements de réception sont aménagés au travers du disque intervertébral, sans résection des plateaux vertébraux 51. Les vertèbres 50 sont ensuite distractées au moyen d'une cale 60 insérée dans l'un des logements puis une cage 1 est insérée dans l'autre logement au moyen de l'instrument 20.

Après mise en place de la première cage 1, la cale 60 est  
30 retirée ; la seconde cage 1 est alors mise en place dans le second logement avec bourrage de copeaux d'os spongieux autour d'elle.

Comme indiqué précédemment, l'invention fournit une cage intervertébrale présentant, par rapport aux cages homologues de la technique antérieure, l'avantage essentiel d'être à la fois peu invasive,  
35 c'est-à-dire de limiter les opérations à accomplir pour l'aménagement du logement de réception de cette cage, de présenter un risque limité

## 6

d'insertion dans les plateaux vertébraux et de garantir l'obtention d'une fusion parfaitement solide des vertèbres.

Il va de soi que l'invention n'est pas limitée à la forme de réalisation décrite ci-dessus à titre d'exemple mais qu'elle en embrasse au contraire toutes les variantes de réalisation visées par les revendications ci-annexées.

## REVENDICATIONS

1 - Cage intervertébrale, présentant une forme allongée et délimitant quatre faces latérales (2, 3), à savoir deux faces latérales principales (2), placées parallèlement à l'axe de la colonne vertébrale lorsque la cage (1) est mise en place et définissant entre elles l'épaisseur de la cage, et deux faces latérales secondaires (3), reliant les deux faces principales (2) l'une à l'autre et destinées à venir en contact avec les vertèbres (50) ; lesdites faces secondaires (3) présentent, vues selon une direction perpendiculaire auxdites faces principales (2), une courbure de forme convexe correspondant à la forme concave que présentent les plateaux vertébraux (51) dans le plan antéro-postérieur, et l'épaisseur de la cage (1) est réduite, c'est-à-dire peut aller de 3,5 à 7 mm ;

cage caractérisée en ce qu'elle présente, au niveau d'au moins une desdites faces secondaires (3), une rainure longitudinale (4) aménagée dans la zone médiane de cette face secondaire (3), et en ce qu'elle a une forme courbe au niveau de cette même face, vue dans la direction longitudinale de la cage (1).

2 - Cage intervertébrale selon la revendication 1, caractérisée en ce qu'elle présente ladite rainure (4) et ladite forme courbe au niveau de ses deux faces secondaires (3).

3 - Cage intervertébrale selon la revendication 1 ou la revendication 2, caractérisée en ce qu'elle présente au moins une série d'entailles (5) au niveau d'au moins une de ses faces secondaires (3), ces entailles (5) étant conformées pour délimiter des dents favorisant une légère insertion de la cage (1) dans les plateaux vertébraux (51).

4 - Cage intervertébrale selon l'une des revendications 1 à 3, caractérisée en ce qu'au moins une de ses parois principales et/ou secondaires comprend au moins un trou (15) destiné à être envahi par les cellules osseuses lors de leur croissance.

5 - Cage intervertébrale selon l'une des revendications 1 à 4, caractérisée en ce qu'elle est percée longitudinalement d'un trou (10) qui débouche dans l'une de ses faces d'extrémité, et en ce qu'elle comprend des cannelures (11) aménagées dans la paroi qui délimite ce trou (10).

## 8

6 - Cage intervertébrale selon la revendication 5, caractérisée en ce qu'elle présente un alésage taraudé (12) dans le fond dudit trou (10), coaxial à ce trou (10).

5 7 - Instrument de mise en place de la cage (1) selon la revendication 6, caractérisée en ce qu'il comprend deux pièces (25, 26), à savoir :

- une pièce tubulaire (25), dont une extrémité (27) comprend une forme correspondant à celle dudit trou (10) et desdites cannelures (11), et
- 10 - une tige (26) engagée et pouvant coulisser dans cette pièce tubulaire (25), dont une extrémité (28) comprend un filetage permettant son engagement dans ledit alésage taraudé (12).



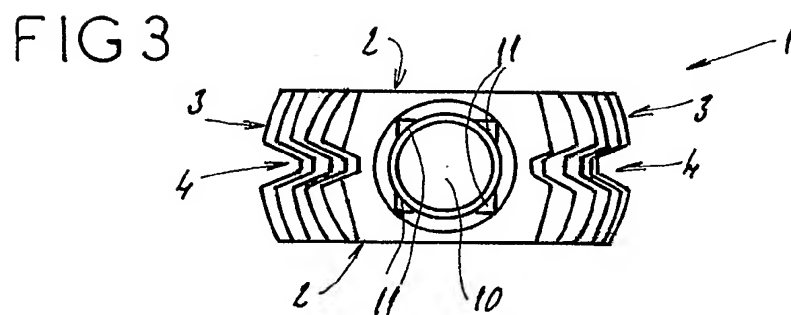
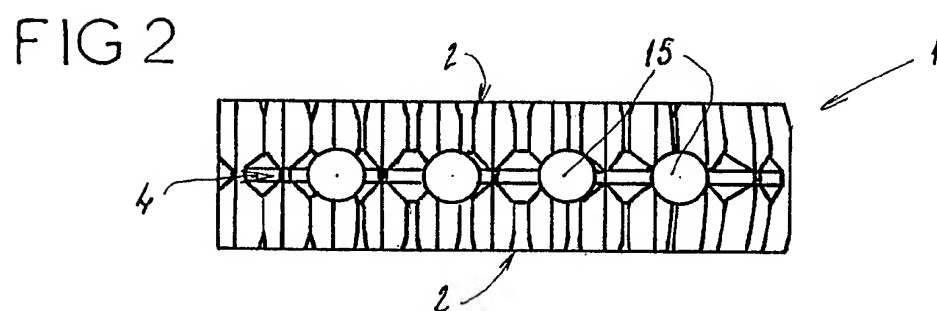
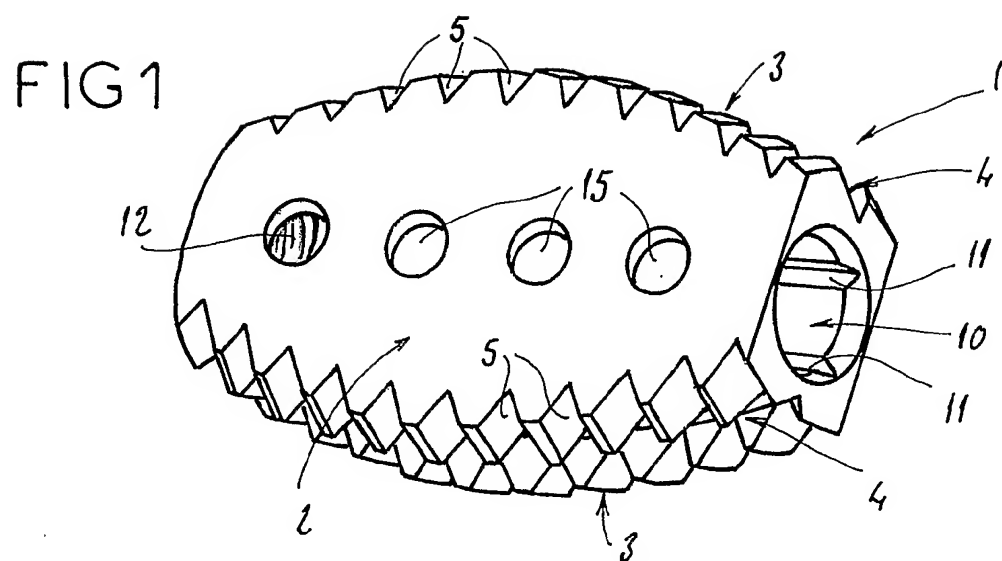


FIG 4

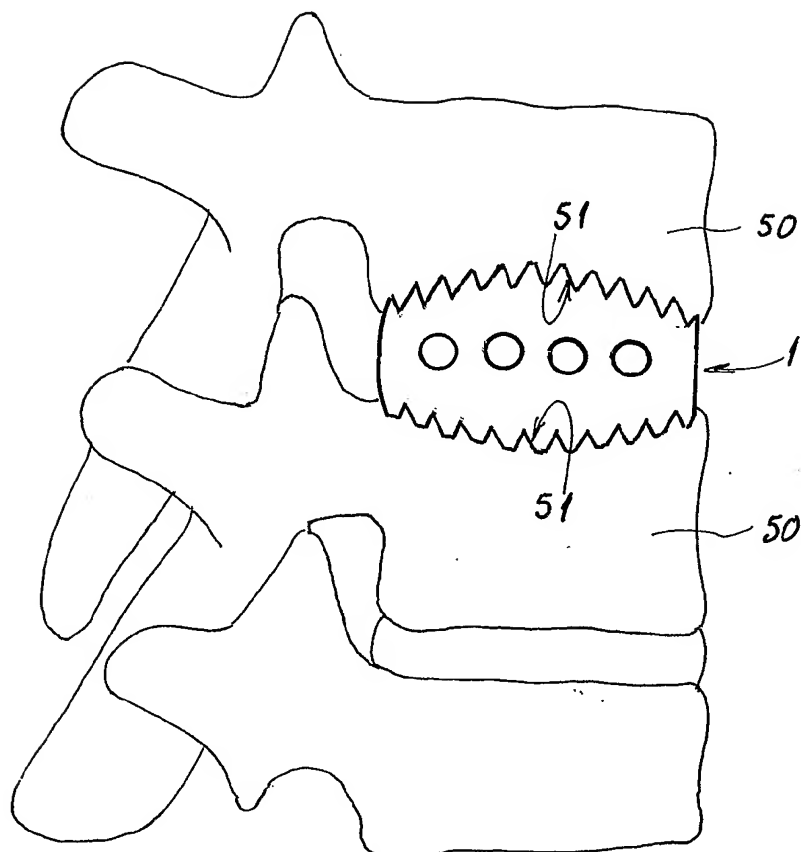
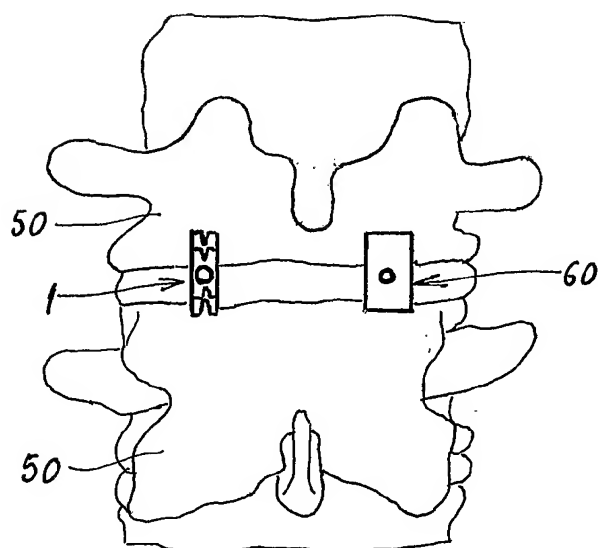
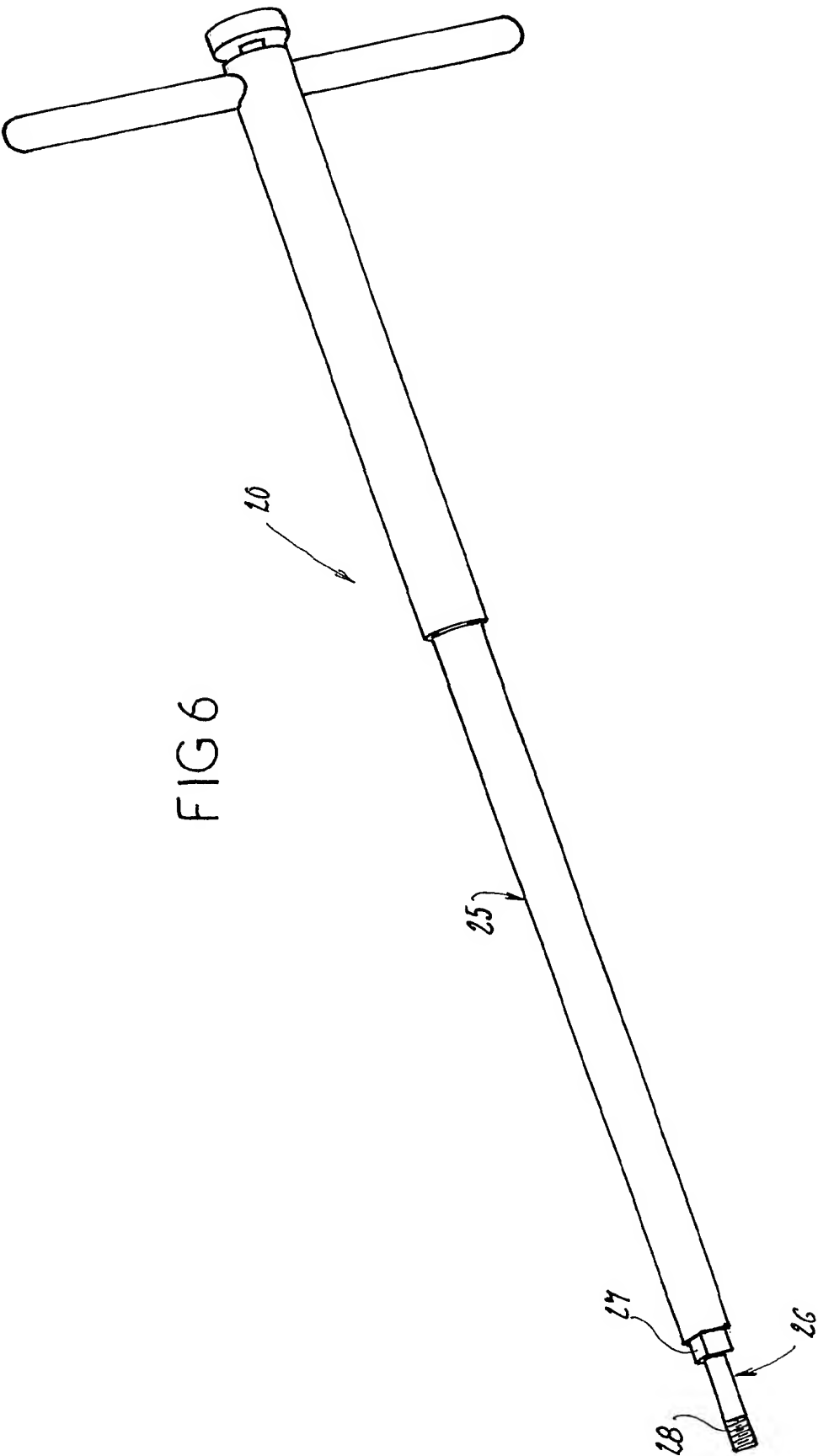


FIG 5





## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/FR 01/03391

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61F2/44 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|------------|--|-----------------------|
| X          | WO 95 08306 A (BECKERS LOUIS FRANCOIS CHARLES ;SYNTHES AG (CH); SCHLAEPFER JOHANN) 30 March 1995 (1995-03-30)<br>claims 30,33; figures 4-9,15-17<br>page 10, paragraph 4 -page 11, paragraph 1 | 1-4                   |
| A          | ---  | 5,7                   |
| X          | US 6 080 158 A (LIN CHIH-I)<br>27 June 2000 (2000-06-27)<br>figures 1-5<br>column 2, line 60 -column 3, line 38  | 1-3                   |
| A          | ---  | 5-7                   |
| A          | EP 0 834 295 A (LUCET ALAIN ;MEDINOV AMP (FR); KERBOUL BERNARD (FR); PERE CHRISTIA)<br>8 April 1998 (1998-04-08)<br>claims 1,7; figures<br>---   | 1-7                   |
|            | ---<br>-/--  |                       |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

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Date of the actual completion of the international search

11 February 2002

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# INTERNATIONAL SEARCH REPORT

Int. Patent Application No.  
PCT/FR 01/03391

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                 | Relevant to claim No. |
|------------|--|-----------------------|
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| A          | FR 2 782 632 A (MATERIEL ORTHOPEDIQUE EN<br>ABREG) 3 March 2000 (2000-03-03)<br>figures 6,7<br>--- | 7                     |
| A          | FR 2 726 759 A (ATLAS IMPLANTS)<br>15 May 1996 (1996-05-15)<br>-----                               |                       |

# INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/FR 01/03391

| Patent document<br>cited in search report |   | Publication<br>date | Patent family<br>member(s)   | Publication<br>date  |
|---|---|---------------------|--|--|
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| FR 2726759                                | A | 15-05-1996          | FR 2726759 A1<br>EP 0793463 A1<br>WO 9614809 A1  | 15-05-1996<br>10-09-1997<br>23-05-1996   |

# RAPPORT DE RECHERCHE INTERNATIONALE

De: internationale No

PCT/FR 01/03391

**A. CLASSEMENT DE L'OBJET DE LA DEMANDE**  
CIB 7 A61F2/44 A61F2/46

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

**B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE**

Documentation minimale consultée (système de classification suivi des symboles de classement)

CIB 7 A61F

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)

EPO-Internal

**C. DOCUMENTS CONSIDERES COMME PERTINENTS**

| Catégorie ° | Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents   | no. des revendications visées |
|-------------|--|-------------------------------|
| X           | WO 95 08306 A (BECKERS LOUIS FRANCOIS CHARLES ;SYNTHE AG (CH); SCHLAEPFER JOHANN) 30 mars 1995 (1995-03-30)<br>revendications 30,33; figures 4-9,15-17<br>page 10, alinéa 4 -page 11, alinéa 1 | 1-4                           |
| A           | ---  | 5,7                           |
| X           | US 6 080 158 A (LIN CHIH-I)<br>27 juin 2000 (2000-06-27)<br>figures 1-5<br>colonne 2, ligne 60 -colonne 3, ligne 38  | 1-3                           |
| A           | ---  | 5-7                           |
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☒ Voir la suite du cadre C pour la fin de la liste des documents

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# RAPPORT DE RECHERCHE INTERNATIONALE

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PCT/FR 01/03391

| C.(suite) DOCUMENTS CONSIDERES COMME PERTINENTS |   |                               |
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| Catégorie *                                     | Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents    | no. des revendications visées |
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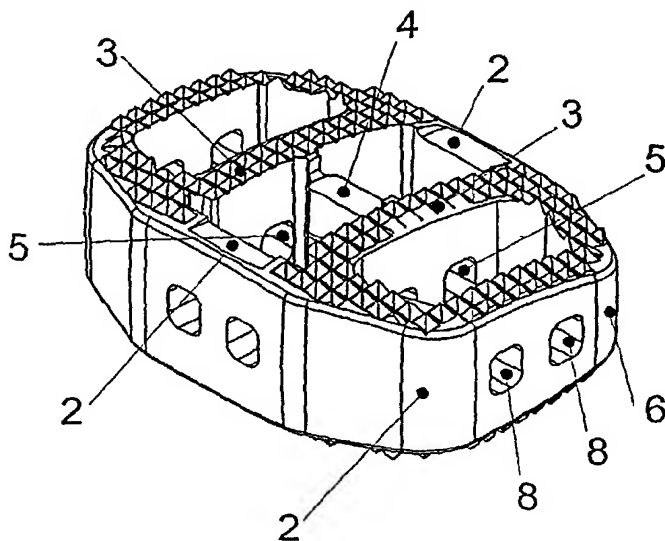
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[Fortsetzung auf der nächsten Seite]

(54) Title: BONE IMPLANT, IN PARTICULAR, AN INTER-VERTEBRAL IMPLANT

(54) Bezeichnung: KNOCHENIMPLANTAT, INSBESONDERE ZWISCHENWIRBELIMPLANTAT



(57) Abstract: The inter-vertebral implant is made from a radiation-transparent material and embodied as an annular hollow body (1). Said implant comprises a sleeve (6) in the form of a hollow cylindrical section, comprising a front (9), a rear (10) and two lateral sections (11) and defines a cylindrical axis (7). The hollow body (1) is divided by two intermediate walls (3), running essentially parallel to the cylinder axis (7) and connecting the front section (9) with the rear section (10) of the sleeve. The surface (2) of the bone implant comprises a surface roughness of at least 2  $\mu\text{m}$ . This surface roughness permits the newly growing bone a better fixation to the implant, in other words a better bone integration.

(57) Zusammenfassung: Das Zwischenwirbelimplantat besteht aus einem strahlendurchlässigen Material und ist als ringförmiger Hohlkörper (1) ausgebildet. Es besitzt einen hohlzylinderabschnittförmigen Mantel (6), der einen vorderen (9), einen hinteren

(10) und zwei seitliche Abschnitte (11) umfasst sowie eine Zylinderachse (7) definiert. Der Hohlkörper (1) ist durch zwei Zwischenwände (3) unterteilt, welche im wesentlichen parallel zur Zylinderachse (7) verlaufen und den vorderen Abschnitt (9) mit hinteren Abschnitt (10) des Mantels verbinden. Die Oberfläche (2) des Knochenimplantats weist eine Oberflächenrauigkeit von mindestens 2  $\mu\text{m}$  auf. Diese Oberflächenrauigkeit erlaubt dem neu gewachsenen Knochen eine bessere Verankerung am Implantat, d.h. eine bessere Knochenintegration.



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**Veröffentlicht:**

- mit internationalem Recherchenbericht
- mit geänderten Ansprüchen

*Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.*

Knochenimplantat, insbesondere Zwischenwirbelimplantat

Die Erfindung betrifft ein Knochenimplantat, insbesondere ein Zwischenwirbelimplantat gemäss dem Oberbegriff des Patentanspruchs 1 sowie ein Verfahren zur Herstellung des Knochenimplantats gemäss dem Oberbegriff des Patentanspruchs 16.

Aus der FR-A-2 703 580 ROBERT ist ein derartiges Knochenimplantat bekannt. Die Nachteile dieses bekannten Zwischenwirbelimplantats bestehen darin, dass

A) die glatte Oberfläche der mit groben Rippen versehenen Deck- und Grundflächen des Implantats, welche mit den Endplatten der benachbarten Wirbelkörper in Kontakt treten, kein optimales Anwachsen des Knochengewebes bewirken, und dass

B) bei Verwendung eines Füllmaterials im Hohlraum des Implantats, dieses wegen der glatten Innenwände leicht herausfallen kann.

Die obenstehende Diskussion des Standes der Technik erfolgt lediglich zur Erläuterung des Umfeldes der Erfindung und bedeutet nicht, dass der zitierte Stand der Technik zum Zeitpunkt dieser Anmeldung oder ihrer Priorität auch tatsächlich publiziert oder öffentlich bekannt war.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt das Problem zugrunde, ein Knochenimplantat, insbesondere ein Zwischenwirbelimplantat zu schaffen, welches eine für das Anwachsen von Knochengewebe optimale Oberflächenstruktur aufweist.

Die Erfindung löst die gestellte Aufgabe mit einem Knochenimplantat, welches die Merkmale des Anspruchs 1 aufweist und einem Verfahren, welches die Merkmale des Anspruchs 16 aufweist.

Die erfindungsgemässe Oberflächenrauigkeit von mindestens 2  $\mu\text{m}$  erlaubt dem neu gewachsenen Knochen eine bessere Verankerung am Implantat, d.h. eine bessere Knochenintegration.

Eine bevorzugte Weiterbildung besteht darin, dass der Hohlkörper durch mindestens zwei Zwischenwände unterteilt ist, wobei die Zwischenwände vorzugsweise mittels einer Querstrebe miteinander verstrebt sind. Diese Zwischenwände erhöhen die Auflageflächen auf den benachbarten Endplatten der Wirbelkörper und reduzieren damit die Flächenpressung und verhindern das Einsinken des Implantats in die benachbarten Wirbelkörper. Zudem erlauben die dazwischenliegenden Hohlräume das Durchwachsen des Implantats mit knöcherner Struktur.

Eine weitere bevorzugte Weiterbildung besteht darin, dass die Oberflächenrauigkeit weniger als 10  $\mu\text{m}$  beträgt. Eine zu grosse Oberflächenrauigkeit schwächt die verbleibenden Spitzen, was wiederum zu Osteolysen führen kann und damit die Arthrodeese beeinträchtigen würde.

Eine weitere bevorzugte Weiterbildung besteht darin, dass die Zwischenwände mit Perforationen versehen sind, welche vorzugsweise eine Mindestfläche von 3,5  $\text{mm}^2$  aufweisen. Die Perforationen der Seitenwände dienen der räumlichen Verankerung der neu gewachsenen knöchernen Struktur und auch einer gegebenenfalls primär eingebrachten Füllmasse.

Eine weitere bevorzugte Weiterbildung besteht darin, dass die seitliche Abschnitte des Mantels des Hohlkörpers Perforationen aufweisen, welche vorzugsweise eine Mindestfläche von 3,5  $\text{mm}^2$  aufweisen. Die Perforationen der seitlichen Abschnitte des Mantels dienen der räumlichen Verankerung der neu gewachsenen knöchernen Struktur und primär auch der Implantathalterung während des Einsetzens des Implantates.

Eine weitere bevorzugte Weiterbildung besteht darin, dass das strahlendurchlässigen Material aus folgender Gruppe ausgewählt ist Polyaryletherketon (PAEK), Polyetherimid (PEI), Polyoxymethylen (POM), flüssigkristallines Polymer (LCP), Polymethylpenten (PMP), Polysulfon (PSU), Polyäthersulfon (PESU oder PES), Polyäthylenterephthalat (PETP), Polymethylmethacrylat (PMMA) und ultrahochmolekulares Polyäthylen (UHMW-PE).

Alle diese bevorzugten Materialien sind elastisch, verfügen aber über unterschiedliche, mechanische Eigenschaften, wie Elastizität (Steifigkeit) und auch Festigkeit. Im Vergleich zu anderen Polymeren weisen sie zum Teil günstige Kriecheigenschaften aus oder zeigen eine geringe Wasseraufnahme. Damit ist je nach Anwendungsbedarf eine optimale Auswahl möglich.

Eine weitere bevorzugte Weiterbildung besteht darin, dass das strahlendurchlässige Material faserverstärkt ist, vorzugsweise mit Kohlefasern oder mit PEEK-Fasern. Eine Faserverstärkung des strahlendurchlässigen Materials versteift die mechanischen Eigenschaften im allgemeinen oder gezielt.

Eine weitere bevorzugte Weiterbildung besteht darin, dass das Verhältnis  $V:v$  zwischen Gesamtvolumen  $V$  des Knochenimplantats und dem Volumen  $v$  des Hohlkörpers im Bereich von 1,9 bis 2,3 liegt. Es hat sich gezeigt, dass dieses Verhältnis die Vorteile eines mechanisch stabilen Implantats mit einem maximalen Volumen von neu gewachsener, knöcherner Struktur vereinigt.

Eine weitere bevorzugte Weiterbildung besteht darin, dass die Oberfläche des Implantats mindestens teilweise mit einer röntgenstrahlendurchlässigen Beschichtung oder einer dünnen, die Röntgenstrahlendurchlässigkeit nicht beeinflussenden Beschichtung versehen ist. Der Vorteil der röntgentransparenten Beschichtung sichert die Beobachtungsmöglichkeiten während des Heranwachsens der Arthrode. Während sich reines PEEK bereits durch eine hervorragende Biokompatibilität auszeichnet, steigert eine

zusätzliche Beschichtung aus einem geeigneten Werkstoff die mechanischen Eigenschaften und die Interfaces zwischen dem neu gewachsenen Knochen und dem Implantat. Als Beschichtungsmaterial eignen sich vorzugsweise Metalle (in einer sehr geringen Dicke, welche die Röntgenstrahlendurchlässigkeit nicht wesentliche beeinträchtigt. Insbesondere eignen sich Titan, Gold oder Platin oder andere geeignete Implantatmetalle.

Eine weitere bevorzugte Weiterbildung besteht darin, dass die Beschichtung aus einem keramischen Stoff besteht, vorzugsweise aus Hydroxylapatit oder Tricalciumphosphat. Beide Keramiken, Hydroxylapatit und Tricalciumphosphat, die sich für eine Beschichtung eignen, zeichnen sich durch den Vorteil aus, dass sie vollständig in den Knochen integriert werden oder sogar durch neues, natürliches Knochengewebe ersetzt werden.

Eine weitere bevorzugte Weiterbildung besteht darin, dass der Hohlkörper mindestens teilweise mit einem Füllmittel aus Calciumphosphat, vorzugsweise Hydroxylapatit oder Tricalciumphosphat gefüllt ist. Damit wird eine bessere, störungsfreiere Kontrolle der Arthrodeese erzielt. Der Hohlkörper kann auch mit einem Füllmittel aus Calciumsulfat, demineralisiertem Knochen, autologem Knochen oder korallinen Substanzen gefüllt werden.

Eine weitere bevorzugte Weiterbildung besteht darin, dass der Hohlkörper (1) mindestens teilweise mit einem röntgenopaken Füllmittel aus einem resorbierbaren, vorzugsweise porösen



Polymer gefüllt ist. Um das Füllmittel röntgenopak zu gestalten, werden dem Polymer Kontrastmittel zugesetzt. Bei PLA kann man z.B. einen Marker, wie z.B. Zirkondioxid zusetzen, zu PEEK kann Bariumsulfat beigemischt werden.

Eine weitere bevorzugte Weiterbildung besteht darin, dass die gegebenenfalls vorhandenen Perforationen im Implantat mindestens teilweise mit dem röntgenopaken Füllmittel gefüllt sind. Dadurch wird das Füllmittel am Herausfallen gehindert.

Das Verfahren zur Herstellung eines erfindungsgemässen Knochenimplantats besteht darin, dass der ringförmige Hohlkörper durch Spritzgiess-, Warmform-, oder Warmpress-Technik hergestellt wird. Durch die Warmverformung wird das Polymer in allen Formelementen verdichtet, was sich insbesondere durch eine bessere Ermüdungsfestigkeit auszeichnet.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellung eines Ausführungsbeispiels noch näher erläutert.

Es zeigen:

Fig. 1 die perspektivische Darstellung eines erfindungsgemässen Zwischenwirbelimplantats;

Fig. 2 eine Aufsicht auf das Implantat gemäss Fig. 1;

Fig. 3 eine Vorderansicht des Implantats gemäss Fig. 1;  
und

Fig. 4 eine Seitenansicht des Implantats gemäss Fig. 1.

Das in den Figuren 1 bis 4 dargestellte Zwischenwirbelimplantat besteht aus einem strahlendurchlässigen Material (PEEK, welches wahlweise mit Kohlefasern oder Glasfasern verstärkt sein kann), welches im Spritzgussverfahren als ringförmiger Hohlkörper 1 ausgebildet ist. Es umfasst einen hohlzylinderabschnittförmigen Mantel 6, der einen vorderen Abschnitt 9 einen hinteren Abschnitt 10 und zwei seitliche Abschnitte 11 aufweist sowie eine Zylinderachse 7 definiert.

Der Hohlkörper 1 ist durch zwei Zwischenwände 3, welche im wesentlichen parallel zur Zylinderachse 7 verlaufen und den vorderen Abschnitt 9 mit dem hinteren Abschnitt 10 des Mantels verbindet, in Kammern unterteilt. Die beiden Zwischenwände 3 sind mittels einer Querstrebe 4 miteinander verstrebt. Die Zwischenwände 3 sind mit Perforationen 5 versehen, welche eine Fläche von ca. 10 mm<sup>2</sup> aufweisen. Auch die seitliche Abschnitte 11 des Mantels 6 weisen Perforationen 8 auf, welche eine Fläche von ca. 10 mm<sup>2</sup> aufweisen.

Die Oberfläche 2 des Knochenimplantats weist eine Oberflächenrauigkeit von 6 µm auf und ist mit einer dünnen, röntgenstrahlendurchlässigen Beschichtung aus Gold versehen.

Das Verhältnis  $V:v$  zwischen Gesamtvolumen  $V$  des Knochenimplantats und dem Volumen  $v$  des Hohlkörpers 1 beträgt ca. 2,1.

Der Hohlkörper 1 kann mit einem röntgenopaken Füllmittel aus Hydroxylapatit aufgefüllt sein, wobei darauf zu achten ist, dass vorzugsweise auch die vorhandenen Perforationen 5;8 mit dem röntgenopaken Füllmittel gefüllt sind.

Patentansprüche

1. Knochenimplantat, insbesondere Zwischenwirbelimplantat, welches aus einem strahlendurchlässigen Material besteht und als ringförmiger Hohlkörper (1) ausgebildet ist mit einem hohlzylinderabschnittförmigen Mantel (6), der einen vorderen (9), einen hinteren (10) und zwei seitliche Abschnitte (11) umfasst sowie eine Zylinderachse (7) definiert, wobei der Hohlkörper (1) durch mindestens eine Zwischenwand (3) unterteilt ist, welche im wesentlichen parallel zur Zylinderachse (7) verläuft und den vorderen Abschnitt (9) mit dem hinteren Abschnitt (10) des Mantels verbindet,

**dadurch gekennzeichnet, dass**

die Oberfläche (2) des Knochenimplantats eine Oberflächenrauigkeit von mindestens 2  $\mu\text{m}$  aufweist.

2. Knochenimplantat nach Anspruch 1, dadurch gekennzeichnet, dass der Hohlkörper (1) durch mindestens zwei Zwischenwände (3) unterteilt ist, wobei die Zwischenwände (3) vorzugsweise mittels einer Querstrebe (4) miteinander verstrebt sind.

3. Knochenimplantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Oberflächenrauigkeit weniger als 10  $\mu\text{m}$  beträgt.

4. Knochenimplantat nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Zwischenwände (3) mit Perforationen (5) versehen sind, welche vorzugsweise eine Mindestfläche von  $3,5 \text{ mm}^2$  aufweisen.

5. Knochenimplantat nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass die seitliche Abschnitte (11) des Mantels (6) Perforationen (8) aufweisen, welche vorzugsweise eine Mindestfläche von  $3,5 \text{ mm}^2$  aufweisen.

6. Knochenimplantat nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass das strahlendurchlässige Material aus folgender Gruppe ausgewählt ist: Polyaryletherketon (PAEK), Polyetherimid (PEI), Polyoxymethylen (POM), flüssigkristallines Polymer (LCP), Polymethylpenten (PMP), Polysulfon (PSU), Polyäthersulfon (PESU oder PES), Polyäthylenterephthalat (PETP), Polymethylmethacrylat (PMMA) und ultrahochmolekulares Polyäthylen (UHMW-PE).

7. Knochenimplantat nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass das strahlendurchlässigen Material faserverstärkt ist, vorzugsweise mit Kohlefasern, Glasfasern oder PEEK-Fasern.

8. Knochenimplantat nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass das Verhältnis  $V:v$  zwischen Gesamtvolumen  $V$  des Knochenimplantats und dem Volumen  $v$  des Hohlkörpers (1) im Bereich von 1,9 bis 2,3 liegt.

9. Knochenimplantat nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass seine Oberfläche mindestens teilweise mit einer röntgenstrahlendurchlässigen Beschichtung oder einer dünnen, die Röntgenstrahlendurchlässigkeit wenig beeinflussenden Beschichtung versehen ist.

10. Knochenimplantat nach Anspruch 9, dadurch gekennzeichnet, dass die Beschichtung aus einem Metall besteht, vorzugsweise aus Titan, Gold oder Platin.

11. Knochenimplantat nach Anspruch 9, dadurch gekennzeichnet, dass die Beschichtung aus einem keramischen Stoff besteht, vorzugsweise aus Hydroxylapatit oder Tricalciumphosphat.

12. Knochenimplantat nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass der Hohlkörper (1) mindestens teilweise mit einem Füllmittel aus Calciumphosphat, vorzugsweise Hydroxylapatit oder Tricalciumphosphat gefüllt ist.

13. Knochenimplantat nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass der Hohlkörper (1) mindestens teilweise mit einem Füllmittel aus Calciumsulfat, demineralisiertem Knochen, autologem Knochen oder korallinen Substanzen gefüllt ist.

14. Knochenimplantat nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass der Hohlkörper (1) mindestens teilweise mit einem Füllmittel aus einem resorbierbaren, vorzugsweise porösen Polymer gefüllt ist.

15. Knochenimplantat nach einem der Ansprüche 4 bis 14, dadurch gekennzeichnet, dass die gegebenenfalls vorhandenen Perforationen (5;8) mindestens teilweise mit dem röntgenopaken Füllmittel gefüllt sind.

16. Verfahren zur Herstellung eines Knochenimplantats gemäss einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, dass der ringförmige Hohlkörper (1) durch Spritzgiess-, Warmform-, oder Warmpress-Technik hergestellt wird.

Patentansprüche

1. Knochenimplantat, insbesondere Zwischenwirbelimplantat, welches aus einem strahlendurchlässigen Material besteht und als ringförmiger Hohlkörper (1) ausgebildet ist mit einem hohlzylinderabschnittförmigen Mantel (6), der einen vorderen (9), einen hinteren (10) und zwei seitliche Abschnitte (11) umfasst sowie eine Zylinderachse (7) definiert,

**dadurch gekennzeichnet, dass**

- A) der Hohlkörper (1) durch mindestens zwei Zwischenwände (3) unterteilt ist, welche im wesentlichen parallel zur Zylinderachse (7) verlaufen und den vorderen Abschnitt (9) mit dem hinteren Abschnitt (10) des Mantels verbinden; und
- B) die Oberfläche (2) des Knochenimplantats eine Oberflächenrauigkeit von mindestens 2  $\mu\text{m}$  aufweist.

2. Knochenimplantat nach Anspruch 1, dadurch gekennzeichnet, dass die Zwischenwände (3) mittels einer Querstrebe (4) miteinander verstrebt sind.

3. Knochenimplantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Oberflächenrauigkeit weniger als 10  $\mu\text{m}$  beträgt.



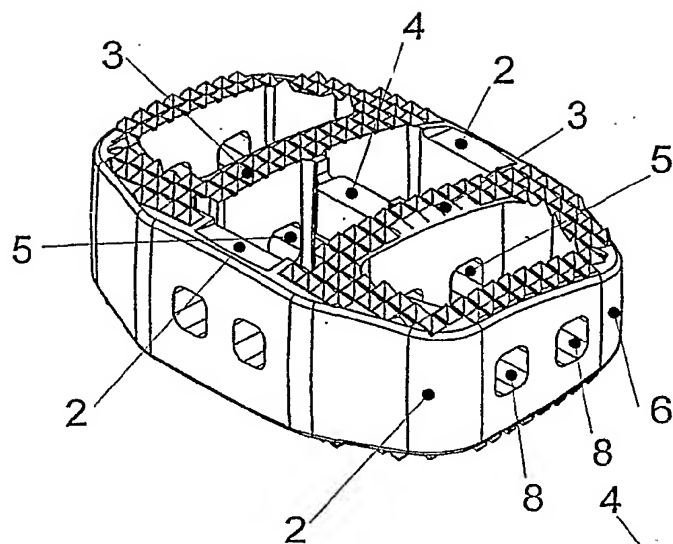


Fig. 1

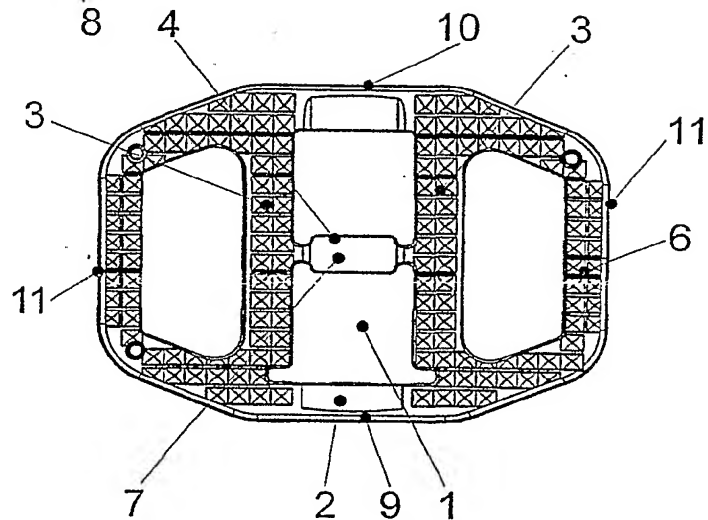


Fig. 2

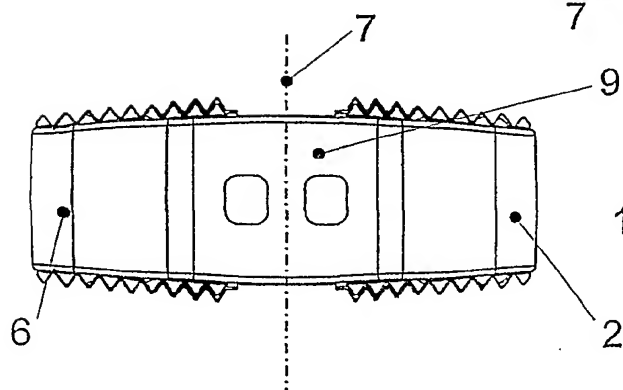


Fig. 3

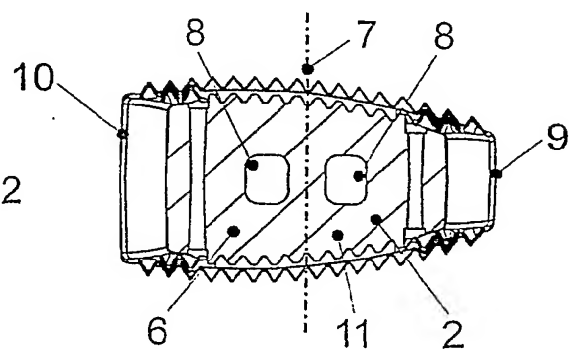


Fig. 4

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/CH 01/00069

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No.     |
|------------|--|---------------------------|
| Y          | WO 00 66045 A (MICHELSON GARY K)<br>9 November 2000 (2000-11-09)<br><br>figures 21-25<br>page 9, paragraph 3 -page 10, paragraph 2<br>page 16, line 3 - line 4<br>page 18, paragraph 1 | 1,2,4,5,<br>7,8,<br>12-16 |
| A          | ---  | 6,9,11                    |
| Y          | WO 97 14377 A (DANEK MEDICAL INC)<br>24 April 1997 (1997-04-24)<br><br>claims 1,3,7,9-11,20,21,24,26,27,31,46;<br>figure 2<br>page 16, line 17 - line 32                               | 1,2,4,5,<br>7,8,<br>12-16 |
| A          | ---  | 3,6,9-11                  |
|            | ---<br>-/--  |                           |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

\* Special categories of cited documents:

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- \* & \* document member of the same patent family

Date of the actual completion of the international search

1 October 2001

Date of mailing of the international search report

09/10/2001

Name and mailing address of the ISA

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Authorized officer

Stach, R

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/CH 01/00069

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|------------|---|-----------------------|
| A          | FR 2 742 653 A (COLORADO)<br>27 June 1997 (1997-06-27)<br>claims 1,11; figures 1,4<br>-----   | 1,2                   |
| A          | US 5 192 327 A (BRANTIGAN JOHN W)<br>9 March 1993 (1993-03-09)<br>figures 1,2,6,7<br>column 3, line 9 - line 18<br>column 5, line 34 - line 57<br>----- | 1,4-8                 |
| A          | WO 99 37255 A (FUSS FRANZ KONSTANTIN<br>;SABITZER RONALD J (AT))<br>29 July 1999 (1999-07-29)<br>claims 11,13-15; figure 2<br>-----                     | 1-5                   |

## INTERNATIONAL SEARCH REPORT

 International Application No  
 PCT/CH 01/00069

| Patent document<br>cited in search report |   | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
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|   |   |                     | ZA 9608726 A               | 21-05-1997          |
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|   |   |                     | DE 69609197 D1             | 10-08-2000          |
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|   |   |                     | AU 2640892 A               | 29-03-1994          |
|   |   |                     | EP 0615428 A1              | 21-09-1994          |
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**A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES**  
 IPK 7 A61F2/44

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

**B. RECHERCHIERTE GEBIETE**

 Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)  
 IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

EPO-Internal

**C. ALS WESENTLICH ANGESEHENE UNTERLAGEN**

| Kategorie* | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile   | Betr. Anspruch Nr.        |
|------------|--|---------------------------|
| Y          | WO 00 66045 A (MICHELSON GARY K)<br>9. November 2000 (2000-11-09)<br><br>Abbildungen 21-25<br>Seite 9, Absatz 3 -Seite 10, Absatz 2<br>Seite 16, Zeile 3 - Zeile 4<br>Seite 18, Absatz 1 | 1,2,4,5,<br>7,8,<br>12-16 |
| A          | ----   | 6,9,11                    |
| Y          | WO 97 14377 A (DANEK MEDICAL INC)<br>24. April 1997 (1997-04-24)<br><br>Ansprüche<br>1,3,7,9-11,20,21,24,26,27,31,46; Abbildung<br>2<br>Seite 16, Zeile 17 - Zeile 32                    | 1,2,4,5,<br>7,8,<br>12-16 |
| A          | -----<br>-/-   | 3,6,9-11                  |



Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen



Siehe Anhang Patentfamilie

\* Besondere Kategorien von angegebenen Veröffentlichungen :

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Datum des Abschlusses der internationalen Recherche

1. Oktober 2001

Absendedatum des internationalen Recherchenberichts

09/10/2001

 Name und Postanschrift der Internationalen Recherchenbehörde  
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 Fax: (+31-70) 340-3016

Bevollmächtigter Bediensteter

Stach, R

## C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

| Kategorie* | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile   | Betr. Anspruch Nr. |
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| A          | WO 99 37255 A (FUSS FRANZ KONSTANTIN<br>;SABITZER RONALD J (AT))<br>29. Juli 1999 (1999-07-29)<br>Ansprüche 11,13-15; Abbildung 2<br>-----                     | 1-5                |

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ationales Aktenzeichen

PCI/CH 01/00069

| Im Recherchenbericht<br>angeführtes Patentdokument |   | Datum der<br>Veröffentlichung | Mitglied(er) der<br>Patentfamilie |             | Datum der<br>Veröffentlichung |
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|  |   |                               | DE                                | 69609197 T2 | 15-03-2001                    |
|  |   |                               | EP                                | 0869753 A1  | 14-10-1998                    |
|  |   |                               | WO                                | 9723175 A1  | 03-07-1997                    |
| US 5192327   | A | 09-03-1993                    | CA                                | 2122336 A1  | 17-03-1994                    |
|  |   |                               | WO                                | 9405235 A1  | 17-03-1994                    |
|  |   |                               | AU                                | 2640892 A   | 29-03-1994                    |
|  |   |                               | EP                                | 0615428 A1  | 21-09-1994                    |
|  |   |                               | AU                                | 665370 B2   | 04-01-1996                    |
|  |   |                               | JP                                | 7504837 T   | 01-06-1995                    |
| WO 9937255   | A | 29-07-1999                    | AT                                | 405367 B    | 26-07-1999                    |
|  |   |                               | AT                                | 11098 A     | 15-12-1998                    |
|  |   |                               | WO                                | 9937255 A1  | 29-07-1999                    |
|  |   |                               | AU                                | 2142099 A   | 09-08-1999                    |
|  |   |                               | EP                                | 1049430 A1  | 08-11-2000                    |





## **RADIALLY EXPANDING INTERBODY SPINAL FUSION IMPLANTS AND INSTRUMENTATION FOR INSERTION THEREOF**

### **BACKGROUND OF THE INVENTION**

#### **Related Applications**

This application claims priority to provisional application no. 60/279,205, filed March 27, 2001, and provisional application serial no. 60/281,714, filed April 4, 2001, both of which are incorporated by reference herein.

#### **Field of the Invention**

The present invention relates generally to interbody spinal implants, and instruments and methods for inserting interbody spinal implants into an implantation space in the spine, and in particular to an expandable interbody (for placement at least in part between adjacent vertebral bodies in the space previously occupied by disc material) spinal fusion implants for the immobilization of adjacent vertebrae.

#### **Description of the Related Art**

Expandable spinal fusion implants have height raising capabilities that are utilized once the implant is initially positioned. Such height raising capability may be utilized within the spine anteriorly, posteriorly, or both and to various extents, respectively to raise the front or back of the implant. More particularly, such implants have upper and lower surfaces of upper and lower portions that in an insertion position are collapsed relative to one another and in a deployed position are spaced further away from one another than in the collapsed position.

Expandable fusion implants offer the advantage of allowing for the placement of a potentially larger implant through a smaller opening in a patient's body.. The first expandable spinal fusion (allowing for the growth of bone from vertebral body to vertebral body through the implant) implant was invented by Michelson and also is disclosed in U.S. Patent No. 5,776,199, filed June 28, 1988, which is hereby incorporated by reference herein.

Expandable interbody spinal fusion implants preferably may be inserted from an anterior approach to the spine, an approach posterior to the vertebral

transverse processes, or to either side of the spinal midline in pairs. Such expandable implants are adapted to increase in height at their leading ends or at their trailing ends from a collapsed state to an expanded state for the purpose of increasing spinal lordosis at that interspace. During installation of expandable interbody spinal fusion implants, it is desirable that the surgeon have the ability to precisely control the implant with the appropriate instruments and methods to load the implant with appropriate bone growth promoting material, to insert the implant into the implantation space, to deploy the implant to a final expanded state, and to further load the implant with bone growth material if so desired.

Also known in the art are expandable interbody spinal fusion implants that are circumferentially expandable at one of their leading or trailing ends to expand both the height and the width of the implant. Such implants have an expansion mechanism that is moved from the trailing end through the interior of the implant to reach the leading end to expand the implant. Any bone growth material present within the interior of the implant would be forced out of the interior of the implant by the expansion mechanism passing therethrough. Accordingly, such implants cannot be effectively preloaded with bone growth promoting material prior to expansion of the implant.

There exists a need for a circumferentially expanding implant that is substantially hollow and substantially devoid of any elaborate or substantial space occupying expansion mechanism to permit preloading of the implant with bone growth promoting material prior to expansion of the implant. The expansion mechanism would not interfere with the capacity to compressively load osteogenic material such as bone or any other suitable material through the length of the implant and to have it extrude from the implant. The extrusion of the osteogenic material from the implant provides an increased volume of osteogenic material over a greater surface area of the adjacent vertebral bodies adjacent the disc space to be fused and beyond the surface area of contact of the implant to the vertebral bodies themselves. Surrounding the implant itself with additional fusion promoting substances in contact with the adjacent vertebral bodies may enhance the fusion process.

There also exists a need for instruments and methods for use with expandable interbody spinal fusion implants providing for all of the aforementioned needs individually or in combination.

### SUMMARY OF THE INVENTION

Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

The present invention is directed to an interbody spinal fusion implant particularly adapted for anterior, posterior, and posterior lateral interbody spinal fusion; and methods and instrumentation for a preferred insertion of these implants.

The present invention implant is adapted to have a generally constant size at one end while allowing for a generally circumferential increase in size at the opposite end. This feature is particularly useful for posterior lumbar interbody fusion and posterior lateral interbody spinal fusion, where it is desirable to have the vertebral bodies spaced apart more anteriorly than posteriorly to restore the lumbar lordosis. The implant is preferably inserted in a generally cylindrical form or more particularly with the opposed surfaces of the implant adapted to contact each of the opposed adjacent vertebral bodies adjacent to the disc space to be fused being generally parallel. Subsequently, the implant is expanded at the leading end so that the opposed vertebral body engaging surfaces of the implant are then in a generally angular relationship to each other over a substantial portion of the length of the implants. The present invention methods and instrumentation in conjunction with the present invention implant allows for the installation of an implant that in its final implanted form is substantially hollow with the exception of an expander ring which is itself preferably hollow so as to not interfere with the full loading of the implant and the extrusion there through of the selected osteogenic material.

In accordance with the purposes of the present invention, as embodied and broadly described herein, an interbody spinal fusion implant is provided for implantation from at least in part a posterior approach at least in part within and across the height of a disc space between two adjacent vertebral bodies of an adult human spine. The implant includes a body having a leading end for insertion first into the disc space, a trailing end opposite the leading end, and a

mid-longitudinal axis along the length of the body. The body has an upper portion adapted to contact one of the adjacent vertebral bodies, a lower portion opposite the upper portion adapted to contact another one of the adjacent vertebral bodies, and at least one side portion between the upper and lower portions. Each of the upper, lower, and side portions extend from the trailing end of the body and are spaced apart from one another to form a hollow interior therebetween. The hollow interior is configured to hold at least some bone growth promoting material therein. The upper and lower portions are configured to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through the body of the implant. Each of the upper, lower, and side portions are configured to move at least in part in a direction away from the mid-longitudinal axis of the body to allow for expansion of the height and at least a portion of the width of the body. The upper, lower, and side portions have a collapsed position relative to one another allowing for a collapsed height and width of the body, and an expanded position relative to one another allowing for an expanded height and width of the body. The expanded height and width of the body is greater than the collapsed height and width of the body, respectively.

The implant also includes an expander positioned at least in part within the hollow interior. The expander is configured to cooperatively engage an instrument adapted to be inserted through the trailing end of the body to engage and to move the expander from a position proximate the leading end when the body is in the collapsed position away from the leading end and toward the trailing end of the body to place the body in the expanded position. The expander is adapted to contact and to move the upper, lower, and side portions away from the mid-longitudinal axis of the body. The upper, lower, and side portions of the body are adapted to cooperatively engage the expander to locate the expander at a location along the length of the body between and away from each of the leading and trailing ends and to resist dislodgment of the expander from that location when the implant is in use. The expander is adapted to hold at least a portion of the upper, lower, and side portions apart so as to maintain the expanded height and width of the body and to resist the collapse of the body to the collapsed body height and width when the body is in the expanded position.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an interbody spinal fusion

implant is provided for implantation from at least in part an anterior approach at least in part within and across the height of a disc space between two adjacent vertebral bodies of an adult human spine. The body has a base proximate the leading end, an upper portion adapted to contact one of the adjacent vertebral bodies, a lower portion opposite the upper portion adapted to contact another one of the adjacent vertebral bodies, and at least one side portion between the upper and lower portions. Each of the upper, lower, and side portions extend from the base of the body and are spaced apart from one another to form a hollow interior therebetween. Each of the upper, lower, and side portions are configured to move at least in part in a direction away from the mid-longitudinal axis of the body to allow for expansion of the height and at least a portion of the width of the body. The upper, lower, and side portions have a collapsed position relative to one another allowing for a collapsed height and width of the body, and an expanded position relative to one another allowing for an expanded height and width of the body. The expanded height and width of the body is greater than the collapsed height and width of the body, respectively.

The implant also includes an expander at least in part within the hollow interior. The expander is configured to contact an instrument that is adapted to be inserted through the trailing end of the body to move the expander from a position proximate the trailing end when the body is in the collapsed position away from the trailing end and toward the base of the body to place the body in the expanded position. The expander is adapted to contact and to move the upper, lower, and side portions away from the mid-longitudinal axis of the body. The upper, lower, and side portions of the body are adapted to cooperatively engage the expander to locate the expander at a location along the length of the body between and away from each of the leading and trailing ends and to resist dislodgment of the expander from that location when the implant is in use. The expander is adapted to hold at least a portion of the upper, lower, and side portions apart so as to maintain the expanded height and width of the body and to resist the collapse of the body to the collapsed body height and width when the body is in the expanded position.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for inserting at least in part within and across the height of a disc space between

two adjacent vertebral bodies of the human spine a spinal implant having upper and lower portions, and an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position. The apparatus includes an inserter guide having a leading end and a trailing end. The leading end of the inserter guide is configured to cooperatively engage the trailing end of the implant. The inserter guide has a hollow interior forming a passage from the trailing end to the leading end through the inserter guide. The apparatus also includes a post adapted to be inserted at least in part through the trailing end of the implant and into a hollow interior of the implant for moving the expander along at least a portion of the length of the implant between the upper and lower portions of the implant. The post has a leading end configured to cooperatively engage the expander and a trailing end adapted to be coupled to the implant and cooperatively engage an instrument for moving the post. The apparatus also includes an inner shaft that is configured to be inserted at least in part within the passage of the inserter guide. The inner shaft has a leading end and a trailing end. The leading end of the inner shaft is configured to cooperatively engage the trailing end of the post. The inner shaft is adapted to move the post so as to move the expander toward the trailing end of the implant to expand the height and at least a portion of the width of the implant.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for use with a spinal implant having an expander for expanding the height of the implant from a collapsed position to an expanded position. The implant has a leading end for insertion first into a disc space between two adjacent vertebral bodies of the human spine and a trailing end opposite the leading end. The implant has at least upper and lower portions adapted to be moved away from one another by the expander when positioned therebetween. The apparatus includes an elongated shaft having a leading end and a trailing end opposite the leading end, and a mid-longitudinal axis. The apparatus also includes an enlarged head proximate the leading end of the shaft that is configured to be inserted at least in part between the upper and lower portions of the implant. The enlarged head is adapted to move apart the upper and lower portions to release the expander therebetween. The apparatus also includes a projection extending

from the enlarged head that is adapted to cooperatively engage the expander for removal of the expander from within the implant.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for inserting at least in part within and across the height of a disc space between two adjacent vertebral bodies of the human spine a spinal implant having an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position. The implant has upper, lower, and side portions including a plurality of arms separated by spaces. The apparatus includes an inserter having a leading end and a trailing end opposite the leading end. The leading end of the inserter guide has a plurality of spaced apart portions that are configured to fit in the spaces between the arms of the spinal implant to cooperatively engage the inserter to the implant.

In accordance with the purposes of yet a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for holding a spinal implant having an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position. The implant has upper, lower, and side portions comprising a plurality of arms separated by spaces. The apparatus includes a sleeve having a leading end and a trailing end and a passageway from the trailing end to the leading end. The passageway provides access to the implant through the sleeve. The leading end of the sleeve has a plurality of spaced apart portions that are configured to fit in the spaces between the arms of the spinal implant to cooperatively engage the sleeve to the implant.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for use with a spinal implant having an expander for expanding the height of the implant from a collapsed position to an expanded position. The implant has a leading end for insertion first into a disc space between two adjacent vertebral bodies of the human spine and a trailing end opposite the leading end. The implant has at least upper and lower portions adapted to be moved away from one another by the expander when positioned therebetween. The apparatus includes an elongated shaft having a mid-longitudinal axis, a leading end, and a trailing end opposite the leading end. The leading end has a bore therein and an

enlarged head with a collar in movable relationship to the head that permits rotational movement of the head independent of the collar. The collar and the head are configured to be inserted at least in part between the upper and lower portions of the implant. The collar is adapted to bear against and move apart the upper and lower portions of the implant to release the expander therebetween. The apparatus also includes a post that is adapted to be inserted at least in part through the trailing end of the spinal implant for guiding the elongated shaft along the mid-longitudinal axis between the upper and lower portions of the implant. The post has a leading end configured to cooperatively engage the implant and a trailing end that is adapted to be received within the bore of the elongated shaft. The head of the elongated shafted is adapted to rotate about the post.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate the embodiments of the invention and together with the description, serve to explain the principles of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded perspective view of a spinal fusion implant, radial expander of the implant, and threaded post in accordance with a preferred embodiment of the present invention for posterior insertion into the spine;

Fig. 2 is an assembled trailing end perspective view of the embodiment of Fig. 1;

Fig. 3 is a trailing end elevation view of the embodiment of Fig. 2;

Fig. 4 is a side elevation view of the embodiment of Fig. 2;

Fig. 5 is a leading end elevation view of the embodiment of Fig. 2;

Fig. 6 is a leading end elevation view of a radial expander of the implant of Fig. 1;

Fig. 7 is a side elevation view of the radial expander of Fig. 6;

Fig. 8A is a trailing end elevation view of the radial expander of Fig. 6;

Fig. 8B is a trailing end elevation view of a radial expander incorporating two alternative embodiments in accordance with the present invention;



Fig. 9 is a partial side sectional view of the embodiment of Fig. 2 prior to the implant being radially expanded;

Fig. 10 is a partial side sectional view of the embodiment of Fig. 2 with the implant in partial radial expansion;

Fig. 11 is a partial side sectional view of the embodiment of Fig. 2 with the implant in a radially expanded state;

Fig. 12 is a side elevation view of one embodiment of a driver instrument for inserting the implant of Fig. 1;

Fig. 13 is a distal end view of the driver instrument of Fig. 12;

Fig. 14 is a perspective proximal end view of the funnel-shaped end of the driver instrument of Fig. 12;

Fig. 15 is a side elevation view of one embodiment of a rotating instrument used to rotate the threaded post to move the radial expander to radially expand the implant of Fig. 1;

Fig. 16 is a side elevation view of one embodiment of a plunger instrument for inserting bone growth promoting material into the implant of Fig. 1 and the disc space;

Fig. 17 is a side elevation view of the plunger instrument of Fig. 16 in an extended state;

Fig. 18 is a perspective view of the posterior aspect of a lumbar segment of a spine with the dural sac retracted to the left showing a partial discectomy and an expandable guard with disc penetrating extensions approaching the disc space between the adjacent vertebral bodies with the disc penetrating extensions in an insertion position;

Fig. 19 is a side view of the guard of Fig. 18 being inserted within the spine with the disc penetrating extensions parallel to one another in the insertion position;

Fig. 20 is a side view of the guard of Fig. 18 in the deployed position with the disc penetrating extensions shown in an expanded position to induce angulation of the adjacent vertebral bodies;

Fig. 21 is a side view of the guard of Fig. 18 in the deployed position with the disc penetrating extensions in an expanded position to induce angulation of the adjacent vertebral bodies and in partial cross-section to show a side view of a drill being inserted through the guard;

Fig. 22 is a side view of the guard of Fig. 18 in partial cross-section showing the spinal fusion implant of Fig. 1 and the driver instrument of Fig. 12 passing through the guard to install the implant into a prepared implantation space across the height of the restored disc space and into the adjacent vertebral bodies;

Fig. 23 is a side view of the implant of Fig. 1 in a non-expanded state inserted into the implantation space and the rotating instrument of Fig. 15 passing through the driver instrument of Fig. 12 and guard of Fig. 18 both shown in partial cross section to engage the threaded post;

Fig. 24 is a side view of the implant of Fig. 1 radially expanded in the implantation space via the rotating instrument of Fig. 15 that passes through the driver instrument and guard both shown in partial cross section;

Fig. 25 is a side view of the rotating instrument of Fig. 15 removing the threaded post from the implant of Fig. 1 through the driver instrument and guard both shown in partial cross section;

Fig. 25A is an enlarged fragmentary view along line 25A of Fig. 25 showing the cooperative engagement of the driver instrument and threaded post;

Fig. 26 is a partial side sectional view of the guard and driver instrument with the plunger instrument of Fig. 16 inserted therein and being used to fill the interior of the implant of Fig. 1 with bone growth promoting material;

Fig. 27 is a partial side sectional view of the guard and driver instrument with the instrument of Fig. 16 in an extended state inserted therein for delivering bone growth promoting material beyond the radial expander and to regions of the disc space beyond the leading end of the implant not occupied by the implant;

Fig. 28 is a partial side sectional view of the implant of Fig. 1 in an expanded state with the threaded post being partially threaded into the radial expander;

Fig. 29 is a partial side sectional view of the implant of Fig. 1 with the post partially threaded into the radial expander being advanced toward the leading end of the implant to unseat the radial expander and return the implant to the non-expanded state for posterior extraction of the implant from the implantation space;

Fig. 30 is a side elevation view of one embodiment of a remover instrument used to unlock and remove a seated radial expander from an anterior

approach and through the leading end of the implant to place the implant of Fig. 1 into a non-expanded state;

Fig. 31 is a partial side sectional view of the remover instrument of Fig. 30 being used to expand the implant anteriorly to unlock and displace the expander to allow for removal of the implant;

Fig. 32 is a partial side sectional view of the implant shown in Fig. 1 in a non-expanded state with the radial expander being removed from the leading end of the implant by the remover instrument of Fig. 30;

Fig. 33 is an exploded perspective view of a spinal fusion implant, radial expander, and threaded post in accordance with another preferred embodiment of the present invention for anterior insertion into the spine;

Fig. 34 is a side elevation view of the embodiment of Fig. 33;

Fig. 35 is a leading end elevation view of the embodiment of Fig. 33;

Fig. 36 is a trailing end elevation view of the embodiment of Fig. 33;

Fig. 37 is a perspective view of an alternative embodiment of the implant and threaded post of Fig. 33 having two diametrically opposed shortened arms;

Fig. 38 is a perspective view of an alternative embodiment of the implant of Fig. 33 having arms of generally the same length;

Fig. 39 is a trailing end elevation view of the radial expander of Fig. 33;

Fig. 40 is a side elevation view of the radial expander of Fig. 33;

Fig. 41 is a leading end elevation view of the radial expander of Fig. 33;

Fig. 42 is a fragmentary side elevation view of the leading end of one embodiment of a driver instrument for inserting the implant of Fig. 33;

Fig. 43 is a side elevation view of one embodiment of an instrument for holding the implant of Fig. 33 while the radial expander of Fig. 33 is advanced through the interior of the implant;

Fig. 44 is a fragmentary side elevation view in partial cross section of one embodiment of a rotating instrument used to linearly advance the radial expander along the threaded post and into the implant to radially expand the implant of Fig. 33;

Fig. 45 is a fragmentary side elevation view in partial cross section of one embodiment of an instrument for use in removing the post from the implant of Fig. 33;

Fig. 46 is a side elevation view of two adjacent vertebrae and a hollow guard for use in preparing a disc space to receive the implant of Fig. 33;

Fig. 47 is a side elevation view of the adjacent vertebrae and guard of Fig. 46 in partial cross-section and a side view of a drill being inserted through the guard;

Fig. 48 is an exploded side view of the implant of Fig. 33, the instrument of Fig. 42, and an implant receiving space formed across the height of the disc space and the adjacent vertebral bodies shown in partial cross section;

Fig. 49 is a side elevation view of the implant of Fig. 33 in a non-expanded state inserted into the implant receiving space formed across the height of the disc space and two adjacent vertebral bodies in cross section and a fragmentary view of the instrument of Fig. 43 in partial cross section being positioned to engage the arms of the implant with the instrument of Fig. 44 shown in partial cross section being inserted therethrough for cooperative engagement with the post;

Fig. 50 is a side elevation view in partial cross section of the implant of Fig. 33 with the instrument of Fig. 44 in rotational engagement with the post of Fig. 33 moving the radial expander into the implant;

Fig. 51 is a side elevation view in partial cross section of the implant of Fig. 33 with the instrument of Fig. 45 being used to remove the post of Fig. 33 from the implant in the expanded state;

Fig. 52A is a top plan view in partial cross section of a vertebra with two implants of Fig. 33 in an expanded state installed side-by-side into a disc space from an anterior approach with the trailing ends in close proximity to each other and the shortened arms oriented toward the antero-lateral aspects of the vertebral body;

Fig. 52B is a top plan view in partial cross section of a vertebra with two implants of Fig. 33 in an expanded state installed side-by-side into a disc space from an anterior approach with the trailing ends in close proximity to each other in a toed-in orientation and the shortened arms oriented toward the antero-lateral aspects of the vertebral body;

Fig. 53 is a fragmentary top plan view in partial cross section of a vertebra with two implants of Fig. 37 in an expanded state installed side-by-side into a disc

space from an anterior approach with the trailing ends in closer proximity to each other than in Fig. 52A;

Fig. 54 is a side elevation view of a preferred embodiment of a remover instrument used to remove an installed radial expander from an implant to collapse the implant of Fig. 33 into a non-expanded state;

Fig. 55 is a partial side sectional view of the implant of Fig. 33 and the instrument of Fig. 54 being used to unlock the radial expander; and

Fig. 56 is a partial side sectional view of the implant of Fig. 33 with the instrument of Fig. 54 being fully deployed in the implant and a hook being used to extract the radial expander from the implant.

#### DETAILED DESCRIPTION OF THE DRAWINGS

The following description is intended to be representative only and not limiting and many variations can be anticipated according to these teachings, which are included within the scope of this inventive teaching. Reference will now be made in detail to the preferred embodiments of this invention, examples of which are illustrated in the accompanying drawings.

Figs. 1-11 show a preferred embodiment of a radially expandable implant and threaded post used to expand the implant in accordance with the present invention. As shown in Figs. 1-5, implant 100 preferably is a spinal fusion implant adapted to be installed from at least in part a posterior approach to the spine into an implantation space formed across the height of a spinal disc and into two adjacent vertebral bodies. Implant 100 has a body with a trailing end 102, a leading end 104 for insertion first into the disc space, and preferably has a hollow interior 103. Leading end 104 is preferably open to permit access to hollow interior 103 of implant 100 through leading end 104. Hollow interior 103 is preferably configured to hold at least some bone growth promoting material therein.

Implant 100 includes at least upper and lower arcuate portions 106a and 106b adapted to be oriented toward and contact adjacent upper and lower vertebral bodies, respectively, and preferably has opposite sides 108a and 108b. Arcuate portions 106a, 106b and sides 108a, 108b include arms 110 that extend from trailing end 102 along at least a part of the length of the implant toward leading end 104. Arms 110 are preferably separated by a space 112. Spaces

112 may be of different lengths and widths and may, for example, be in the shape of a slit, a slot, or any other shape suitable for the intended purpose of spacing apart arms 110. Preferably, spaces 112 permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through the body of implant 100.

As best shown in Figs. 9-11, arms 110 have an interior surface 114 facing hollow interior 103 of implant 100 configured to bear against and hold a radial expander for forcing apart arms 110 from within hollow interior 103. Preferably, upper portion 106a, lower portion 106b, and at least one of sides 108a, 108b are configured to locate an expander along the length of the body of implant 100 between and away from each of trailing and leading ends 102, 104 and to resist dislodgement of the expander when implant 100 is in use. Interior surface 114 of arms 110 of at least upper and lower arcuate portions 106a, 106b preferably has a ramped portion 116 and seat 118 for receiving an expander 120. Each arm 110 preferably is of such length, thickness, and material to resist rotational torquing forces during rotation of implant 100 while being flexible enough to move in a radial direction away from the mid-longitudinal axis of implant 100 when forced apart from the interior of implant 100. For example, one embodiment of implant 100 has six arms 110, each of which flexes in a radial direction away from the mid-longitudinal axis; thus, each arm 110 moves in a direction different from that of any of the other arms 110 of implant 100. Preferably, each arm 110 is sufficiently resilient so that each arm 110 may be moved away from the mid-longitudinal axis of implant 100 and may be permitted to return to its original orientation if desired without substantial deformation. Examples of preferred materials for arms 110 include, but are not limited to, metals such as titanium and stainless steel, plastics, and carbon fibers among others. Arms 110 may be engineered to have a flexibility and springiness optimal for the stiffness of the area of the spine into which they are to be implanted.

In the expanded position, arms 110 may be at least in part concave along at least a portion of the length of implant 100. A concave configuration of arms 110 provides a desirable springiness and resilience for contacting and supporting the vertebral bodies adjacent implant 100.

Although it is preferred to have movable arms 110 spaced around the entire circumference of the implant, the invention is not so limited. By way of

example only, one or more arms 110 may be truncated or omitted from a side or sides to limit the expansion of the width of the implant. A preferred embodiment of implant 100 would have at least two arms 110 on each of upper and lower arcuate portions 106a, 106b, each of arms 110 being adapted to be radially expanded in a direction away from the mid-longitudinal axis of implant 100. To accommodate side-by-side placement of implants, arms 110 may be of different lengths.

Implant 100 preferably includes at least one external thread 122 to permit for the rotational insertion of implant 100 into the disc space and between adjacent vertebral bodies a human spine. Although a preferred embodiment of the implant includes threads, the invention is not so limited. For example, the exterior of implant 100 may include other bone engaging surfaces such as projections, splines, knurling, ratchets, or other surface roughenings to resist expulsion of the implant from the implantation space after implantation.

As shown in Figs. 1-4, trailing end 102 preferably is configured to cooperatively engage a driver 300 shown in Fig. 12 used to install implant 100 into the disc space. For example, trailing end 102 may include truncated sides 124 for cooperatively engaging flanges 310 of driver 300 and recesses 126a and 126b for engaging pins 312a and 312b, respectively, of driver 300. Trailing end 102 of implant 100 has an opening 128 sized for receiving a post 200 for engagement with radial expander 120.

Post 200 is configured to be inserted into implant 100 through trailing end 102. Post 200 preferably has a shaft 202 with at least one thread 204 and a head 206. Head 206 includes a tool engagement area 208 for cooperatively engaging a tool used for inserting and removing post 200 from implant 100. Area 208 is shown as having a hex-shaped engagement surface, but it is understood that area 208 may have any configuration suitable for its intended purpose. The distal end of post 200 passes through opening 128 of implant 100 and extends into the interior of implant 100 to engage radial expander 120. Thread 204 is adapted to cooperatively engage radial expander 120 to move radial expander toward trailing end 102 of implant 100 and force arms 110 apart to expand implant 100. Shaft 202 may be at least in part smooth to permit movement of shaft 202 within opening 128 without engagement to opening 128.

As shown in Figs. 6-8A, radial expander 120 is configured to be inserted at least in part within hollow interior 103 of implant 100. Expander 120 preferably has a leading face 130 adapted to be oriented toward trailing end 102 of implant 100 and an opposite trailing face 132 adapted to be oriented toward leading end 104 of implant 100 when inserted within hollow interior 103 of implant 100. A preferred radial expander 120 has an opening 134, guide pegs 136, and a rim 138 adapted to bear against interior surface 114 of arms 110. Radial expander 120 is preferably at least in part circular or may have any other configuration suitable for its intended purpose. Opening 134 is preferably threaded to cooperate with thread 204 of post 200 to move radial expander 120 toward trailing end 102 of implant 100. Although threaded rotational engagement is preferred for moving radial expander 120, the invention is not so limited. For example, post 200 may be configured to engage radial expander 120 with a retractable flange or projection and pull expander 120 into position to expand arms 110. Preferably, expander 120 has a fixed shape.

Guide pegs 136 of radial expander 120 are adapted to fit within spaces 112 such that as post 200 is rotated, radial expander 120 advances in a linear direction away from leading end 104 towards trailing end 102 of implant 100. Pegs 136 prevent substantial rotation of radial expander 120 during rotation of post 200. Although two guide pegs 136 are shown extending from radial expander 120, the number and shape of pegs 136 may be varied as suitable for their intended purpose.

Fig. 8B shows a radial expander 120' incorporating two alternative embodiments in accordance with the present invention. Radial expander 120' is adapted to selectively expand the height of implant 100 and to limit or prevent the expansion of the width of implant 100. The configuration of radial expander 120' provides for the selective movement of one or more arms 110 away from the mid-longitudinal axis of implant 100 as radial expander 120' is advanced into implant 100. For example, radial expander 120' may have one or more truncated sides 135 to form a reduced width portion of radial expander 120'. Truncated side 135 is preferably configured to avoid contact with the interior surface 114 of arms 110 adjacent truncated side 135 and is preferably configured to clear interior surface projections such as, for example, ramp 116 of arm 110 during the advancement of radial expander 120' toward leading end 102. Instead of truncated side 135,



radial expander 120' may include a groove 137 configured to receive at least a portion of an arm 110 adjacent thereto. In its preferred use, at least the upper and lower portions of rim 138 of radial expander 120' bear against the interior surface 114 of arms 110 to expand the height of implant 100 so as not to induce expansion of any arm or arms 110 adjacent truncated side 135 or groove 137, as the case may be. The expansion of the implant may be controlled by the interaction of the radial expander and arms of the implant to expand the width to only one side or to expand both sides by different amounts and involve one or more arms on a side of the implant. It is appreciated that other configurations of radial expander 120' are possible to achieve its intended purpose without departing from the scope of the present invention.

Fig. 9 shows implant 100 in a collapsed state. After insertion into the disc space, post 200 is rotated, causing radial expander 120 to travel within the interior of implant 100 from a position proximate leading end 104 toward trailing end 102. Pegs 136 travel within space 112 and can contact the sides of arms 110 to limit rotation of radial expander 120 during rotation of post 200.

Fig. 10 shows rim 138 of radial expander 120 moved along interior surface 114 of implant 100 after post 200 is initially rotated, and shows rim 138 in contact with ramp portions 116 of implant 100. Movement of radial expander 120 away from leading end 104 along ramp portions 116 forces arms 110 to move away from the mid-longitudinal axis of implant 100 and toward the adjacent vertebral bodies.

As shown in Fig. 11, continued rotation of post 200 causes radial expander 120 to traverse ramp portions 116 and enter seat 118 of implant 100. The entrance to seat 118 is narrower than the remainder of seat 118 to prevent radial expander 120 from backing-out. Radial expander 120 is further held into place within seat 118 by arms 110. The sloped sides of seat 118 form an inclined plane that inhibits movement of radial expander 120 toward leading end 104 of implant 100. With radial expander 120 seated in seat 118, arms 110 are forced apart at a greater distance as measured from leading end 104 to the mid-longitudinal axis than from trailing end 102 to the mid-longitudinal axis to place implant 100 into an expanded state. After implant 100 is in the expanded state, post 200 can be removed from implant 100 by rotation in the opposite direction,

and radial expander 120 remains in seat 118 to maintain the expanded height and width of implant 100.

Figs. 12-14 show an implant driver 300 for inserting implant 100 into a disc space. Implant driver 300 has a shaft 302, a distal end 304, and a proximal end 306. Shaft 302 is preferably hollow and is adapted to permit the passage of other instruments therethrough as described below. Distal end 304 includes an implant engaging head 308 with flanges 310, pins 312a, 312b, and an opening 314. Implant engaging head 308 is sized and shaped to cooperatively engage an implant to hold and manipulate the implant during insertion into the disc space. Proximal end 306 includes a handle 316 for rotational and linear advancement of driver 300. Proximal end 306 preferably has a funnel-shaped opening 318 passing through shaft 302 and expanding through distal end 304. Funnel-shaped opening 318 is preferably configured as shown in Fig. 14 to facilitate the introduction of bone growth promoting material into shaft 302. Funnel-shaped opening 318 is preferably sized and shaped to receive other instruments therethrough, such as plunger 500 described in association with Figs. 16 and 17 below.

Fig. 15 shows a rotating tool 400 for engaging and rotating post 200. Rotating tool 400 has a distal end 402 and a proximal end 404. Distal end 402 has a tip 406 adapted to cooperatively engage area 208 of post 200. In a preferred embodiment, tip 406 is hex-shaped, but may be of any shape suitable to engage post 200. Tip 406 is preferably adapted to engage area 208 of post 200 such that upon the disengagement of post 200 from implant 100, rotating tool 400 can withdraw post 200 through shaft 302 of driver 300. In order to facilitate the removal of post 200 such that post 200 and rotating tool 400 may be removed together, tip 406 may be adapted to cooperatively engage with area 208, for example, via an interference fit, detent, or retractable spring flange. Proximal end 404 is preferably configured to engage a handle and has a stop 408. Proximal end 404 is preferably adapted to engage with a mechanical or manual device for rotating shaft 410.

Figs. 16 and 17 show a plunger instrument for inserting bone growth promoting material into implant 100 and into the surrounding disc space. Plunger 500 preferably has an outer shaft 502, an inner rod 504, and a handle 506. Inner rod 504 preferably has a proximal end configured to engage a handle, such as a

T-handle for example, and a stop 508 for limiting the travel of inner rod 504 when placed within outer shaft 502. In use, plunger 500 may be inserted into an instrument adapted to deliver bone growth promoting material into implant 100 such as driver 300. Plunger 500 and driver 300 together may be placed within a guard such as guard 600 of Fig. 18 to introduce bone growth promoting material into hollow interior 103 of implant 100 and preferably the disc space surrounding the implant.

In a preferred embodiment, bone growth promoting material is introduced into hollow interior 103 of shaft 302 of driver 300 through funnel-shaped opening 318. Plunger 500 with inner rod 504 inserted therein, may be inserted into the interior of driver 300 to push bone growth promoting material therethrough and into the implant. Plunger 500 and inner rod 504 may further move bone growth promoting material into the remaining areas inside and around the implant not yet filled with bone growth promoting material.

Plunger 500 preferably has a clamp 510 and stop 508 to limit the extension of inner rod 504 from outer shaft 502. Stop 508 may have any configuration adapted to limit the travel of inner rod 504, for example, a shoulder, flange, or other projection. Although it is preferred that inner rod 504 is solid, the invention is not so limited. Clamp 510 in the tightened position holds inner rod 504 in fixed relationship to outer shaft 502 and preferably so as not to extend from the distal end of shaft 502. When clamp 510 is released, inner rod 504 is permitted to travel beyond the distal end of outer shaft 502 to the extent limited by stop 508.

Figs. 18-30 show various steps of a preferred method for inserting implant 100 and using associated instrumentation disclosed herein.

Fig. 18 is a perspective view of a segment of a spine viewed from a posterior aspect with the dural sac retracted to the left showing that a partial discectomy has already been performed. Guard 600, with disc penetrating extensions 602, 604 and window 606, is shown approaching the disc space between the adjacent vertebral bodies with disc penetrating extensions 602, 604 in a first or insertion position.

It is appreciated that various types of guards may be used to provide protected access to the disc space including, but not limited to, those taught by Michelson in Application Serial Nos. 10/085,731 and 10/085,406; and U.S. Patent

Nos. 5,015,247; 5,484,437; 6,080,155; and 6,210,412 all of which are incorporated herein by reference.

An impaction cap 608 is positioned on the proximal end of guard 600 to maintain it in the open position such that the disc penetrating extensions are closed into the insertion position. In this position, guard 600 is ready to be placed or driven into the disc space between the adjacent vertebral bodies.

In Fig. 19, the extensions of guard 600 are fully inserted into the spine with the disc penetrating extensions parallel to one another in the insertion position. Impaction cap 608 is shown holding the guard in the open position and the disc penetrating extension in the insertion position. Guard 600 rotationally articulates to permit movement of disc penetrating extensions 602, 604 in response to movement of a first portion 610 and a second portion 612 relative to one another. The rotational articulation preferably occurs about a hinge 614, which is preferably formed in first and second portions 610, 612.

In Fig. 20, guard 600 is shown in a closed position with the disc penetrating extensions shown in the inserted position to induce lordosis to the vertebral bodies. After closing guard 600, the proximal end has a lock collar 616 placed around it to maintain guard 600 in the closed position.

In Fig. 21, guard 600 is in a closed position with disc penetrating extensions 602, 604 in the inserted position to induce angulation to the adjacent vertebral bodies. At the distal end of guard 600 shown in cross-section is a side view of a bone removal device such as a drill 700 being inserted through guard 600. It is appreciated that other bone removal devices suitable for the intended purpose such as, but not limited to, burrs, reamers, mills, saws, trephines, chisels, and the like may also be used and would be within the scope of the present invention. Guard 600 provides protected access to the disc space and the adjacent vertebral bodies for drill 700 via the elongated opening in guard 600.

Drill 700 may have a reduced diameter-cutting portion relative to the shaft diameter of guard 600 or may be inserted through an inner sleeve that passes into guard 600 to guide drill 700 to form an implantation space smaller than the passage through guard 600. Thus, the guard opening may be taller than the height of the cutting portion of drill 700. Such a taller opening also allows the implantation of an implant taller than the height of the cutting portion of drill 700.

As best shown in Fig. 22, implant 100 and implant driver 300 may be passed through guard 600 to insert implant 100 in a collapsed position into the disc space between the adjacent vertebral bodies. The guard may be left in place throughout the procedure. Implant 100 is assembled with post 200 inserted through trailing end 102 of implant 100 to engage radial expander 120 inserted in the collapsed position into hollow interior 103 of implant 100 through leading end 104. Radial expander 120 in this position may bear against the interior surface 114 of arms 110 but does not yet force arms 110 apart so that implant 100 is in a non-expanded state. Implant 100 is preferably rotated into the disc space such that thread 122 penetrably engages the bone of the adjacent vertebral bodies.

As illustrated in Fig. 23, after implant 100 is installed in the desired position in the implantation space between the adjacent vertebral bodies with opposed arcuate portions 106a and 106b oriented toward the adjacent vertebral bodies, rotating tool 400 is used to engage and rotate post 200 so as to pull radial expander 120 away from leading end 104 and toward trailing end 102 along the interior surface 114 of arms 110 to transition implant 100 from a collapsed position to an expanded position.

As shown in Fig. 24, as rotating tool 400 is rotated, radial expander 120 moves toward trailing end 102 of implant 100 causing arms 110 to move radially outward away from the mid-longitudinal axis of implant 100. The interaction between radial expander 120 and arms 110 is best shown in Figs. 9-11. The radial expansion of implant 100 results in a greater implant height and width proximate leading end 104 than the implant height and width proximate trailing end 102. Upper and lower arcuate portions 106a, 106b are positioned in angular relationship to each other and position the vertebral bodies adjacent implant 100 in an angular relationship to each other.

As shown in Figs. 25 and 25A, after implant 100 is in the expanded state, post 200 is removed by rotating tool 400 from implant 100. Rotating tool 400 is adapted to cooperatively engage tool engagement area 208 of post 200. The leading end of rotating tool 400 may be tapered to allow the tip of tool 400 to slightly bind and positively engage tool engagement area 208. Radial expander 120 remains seated within hollow interior 103 of implant 100 to hold arms 110 in a radially expanded state.

Figs. 26 and 27 show a preferred method for insertion of bone growth promoting materials into implant 100 and the disc space surrounding implant 100. Driver 300 is shown inserted into guard 600 with its distal end adjacent to and in communication with opening 128 of implant 100 to access hollow interior 103 of implant 100. Bone growth material is introduced into funnel shaped end 318 of driver 300. Plunger 500 with inner rod 504 in the retracted position is used to push and load the bone growth promoting material through shaft 302 of driver 300 and into implant 100. Sufficient bone growth promoting material is introduced into driver 300 to at least partially fill implant 100. Alternatively, the implant may be pre-loaded with bone growth promoting material prior to its insertion into the implantation space. Additional bone growth material may be added to fill any space within the implant created as a result of transitioning implant 100 to an expanded position as described below.

As shown in Fig. 27, after the implant is at least partially filled with bone growth promoting material, inner rod 504 is moved forward in the extended position into implant 100 through opening 128 of trailing end 102 to push the bone growth promoting material in its path through opening 134 of radial expander 120. Distributing bone growth promoting material beyond radial expander 120 fills the interior of implant 100 proximate leading end 104 and introduces bone growth promoting material further into the disc space beyond leading end 104 and unoccupied by implant 100. After inner rod 504 is retracted from within the interior of implant 100 and plunger 500 is removed from driver 300, additional bone growth promoting material may be inserted into driver 300. Plunger 500 then may be used to fill the space left unoccupied by the removal of inner rod 504 with bone growth promoting material and further pack bone growth promoting material into implant 100. After filling implant 100 and the surrounding disc space with bone growth promoting material, plunger 500 and driver 300 are removed from guard 600. The trailing end of guard 600 is then opened to return disc penetrating extensions 602, 604 to the closed position to facilitate the removal of guard 600 from the disc space.

Figs. 28-32 show a preferred remover and methods of disengaging radial expander 120 from seat 118 of implant 100 if it is desired to uninstall implant 100 or other implants of the present invention designed for a generally posterior insertion. Fig. 28 shows post 200 being partially threaded into a seated radial

expander 120 by rotating tool 400 such that a portion of post 200 extends from trailing end 102 of implant 100. As shown in Fig. 29, post 200 may then be advanced in a linear direction without substantial rotation toward leading end 104 of implant 100 such as, for example, with an impaction force. The linear advancement of post 200 toward leading end 104 moves expander 120 out of seat 118 and toward leading end 104. This allows the implant arms to collapse inward to the unexpanded state, thereafter allowing the implant to be unthreaded or otherwise removed from the spine. The implant holder may be attached prior to collapsing the implant or thereafter. With expander 120 removed from the interior of implant 100, arms 110 are no longer held in a radially expanded position, thereby causing implant 100 to collapse to an unexpanded state.

With reference to Figs. 30-32, in certain circumstances, for example, where it may be desirable to revise an instrumentation and to access implant 100 from an anterior aspect of the spine, radial expander 120 may be removed from the leading end 104 (oriented near the anterior aspect of the space) of implant 100. Fig. 30 shows a remover 800 for removing radial expander 120 from hollow interior 103 of implant 100 through leading end 104. Remover 800 has a shaft 802, a distal end 804, and a proximal end 806. Distal end 804 has a threaded rod 808 and an enlarged head 810 with a diameter configured to enter hollow interior 103 of implant 100 in a radially expanded state and force apart arms 110. Proximal end 806 is preferably configured to be attached to a removable handle for rotating remover 800.

Threaded rod 808 of remover 800 threads into radial expander 120 causing forward movement of remover 800 toward leading end 104 of implant 100. As remover 800 moves toward leading end 104, enlarged head 810 contacts interior surface 114 of arms 110, forcing arms 110 to move outward and further away from the mid-longitudinal axis of implant 100. This movement in turn causes seat 118 to expand outward opening the entrance to seat 118, thus permitting radial expander 120 to be removed from seat 118 of implant 100. Fig. 32 shows remover 800 removing radial expander 120 from seat 118 to return arms 110 to their initial non-expanded position. The implant may then be removed from the implantation site if desired.

The method of the present invention may also be performed from an anterior approach to the spine. Figs. 33-56 show various embodiments of an

implant 900 for insertion from at least in part an anterior approach to the spine as well as instruments and the associated method for inserting and removing implant 900. Implant 900 is similar to implant 100, with certain differences noted below. As shown in Figs. 33-36, implant 900 has an open trailing end 902, a leading end 904 shown closed in this embodiment, a base 905 proximate the leading end, and a shortened arm 909 and lengthened arms 910 extending from base 905. Fig. 37 shows an alternative embodiment of implant 900 having two opposed shortened arms 909 and lengthened arms 910. Shortened arms 909 are preferably located on at least one side of implant 900 when two implants are inserted side-by-side as shown in Figs. 52A, 52B, and 53. Shortened arms 909 provide for a reduced diameter of trailing end 902 such that trailing end 902 does not substantially protrude from the disc space to minimize the risk of interference with delicate vascular and neurological structures present adjacent to the disc space. Shortened arms 909 also permit two implants 900 in an expanded state to be placed side-by-side in close proximity to each other in the disc space. Although a combination of shortened arms 909 and lengthened arms 910 is preferred, the invention is not so limited. For example, in situations where the surgeon determines it is appropriate, implant 900 may have arms 910 of generally equal length as shown in another alternative embodiment of implant 900 in Fig. 38.

The interaction between radial expander 920 and the interior surface of arms 909, 910 is similar to that between radial expander 120 and arms 110 (described in relation to Figs. 9-11) except that unlike the interior surface of arm 110, shortened arms 909 have a notched area 917 that functions to hold the radial expander 920 in seat 918 and maintain shortened arms 909 in a radially expanded state when radial expander 920 is seated in seats 918 of lengthened arms 910.

In implant 900 a post 1000 is inserted through the trailing end 902. Leading end 904 preferably has a threaded opening 928 for threadably engaging post 1000. Post 1000 has a shaft 1002 with a first thread 1004 for cooperative engagement with a tool 1300 shown in Fig. 44 for pushing or otherwise moving radial expander 920 away from trailing end 902 and toward base 905 proximate leading end 904 of implant 900. Post 1000 has a head 1006 with a tool engagement area 1008 that is preferably hex-shaped to engage a post remover



1400 shown in Fig. 45, and a second thread 1010 shown in Figs. 50, 51 at the end opposite head 1006 for cooperative engagement with threaded opening 928 in leading end 904 of implant 900.

As an alternative to using a post with a threaded end for engagement with the leading end of the implant, a post may be used having a leading end with a retractable flange or other projection for cooperative engagement with the leading end of the implant. Such a post may then be used to rotate the radial expander into position in a fashion similar to that described with reference to Figs. 23 and 24. Once the radial expander is seated, the flanges or other projections may be retracted, and the post may then be withdrawn.

As shown in Figs. 33 and 39-41, radial expander 920 is similar to radial expander 120 shown in Figs. 6-8. Opening 934 of radial expander 920 is preferably unthreaded. A threaded opening is not essential since radial expander 920 is moved by rotating tool 1300 and not by post 1000, described in more detail below.

Fig. 42 shows an implant driver 1100 for inserting implant 900 into a disc space. Driver 1100 has a shaft 1102 and a distal end 1104. Distal end 1104 preferably has an implant engaging head 1108 with flanges 1110 spaced apart by recessed areas and a bore 1120. Implant engaging head 1108 is preferably sized and shaped to cooperatively engage trailing end 902 of implant 900 for insertion into the disc space. Implant engaging head 1108 preferably is tapered to facilitate insertion into the interior of implant 900 and to facilitate the placement of flanges 1110 into spaces 912. Arms 909, 910 fit into recessed areas between flanges 1110. In this position, driver 1100 is engaged to implant 900 and can rotate implant 900. Bore 1120 is preferably configured to receive post 1000 so that driver 1100 may insert implant 900 with post 1000 already attached thereto.

Fig. 43 shows an implant holder 1200 for holding implant 900 in a stable position while one or more tools, for example rotating tool 1300, engages with post 1000 to move radial expander 920 toward leading end 904. Implant holder 1200 has a distal end 1202, a proximal end 1204, a shaft 1206 therebetween, and a handle 1208. Distal end 1202 preferably has a plurality of flanges 1210 that are configured for engagement with spaces 912 between arms 909, 910. Shaft 1206 is preferably hollow and sized to accommodate the passage of tools therethrough, for example, rotating tool 1300. Flanges 1210 are adapted to fit in

spaces 912 between arms 909, 910 to hold implant 900. Rotating tool 1300 is used to rotate post 1000 to move radial expander 920 while implant 900 is held stable by holder 1200 to resist the rotational forces bearing upon post 1000.

Fig. 44 shows rotating tool 1300 for advancing radial expander 920 away from trailing end 902 and toward base 905 proximate leading end 904. Rotating tool 1300 has a distal end 1302 and a shaft 1310. Distal end 1302 has a bore 1312 with a thread 1314 adapted to cooperatively engage with first thread 1004 of post 1000. Bore 1312 preferably has an unthreaded portion at its leading end that permits rotating tool 1300 to move over a portion of post 1000 such as post head 1006 prior to engagement of the thread. As tool 1300 is rotated onto post 1000, distal end 1302 bears against radial expander 920 to advance radial expander 920 into implant 900. After radial expander 920 is seated into seat 918, rotating tool 1300 is unthreaded from post 1000 and removed from implant 900.

Fig. 45 shows a post remover 1400 for removing post 1000 after radial expander 920 has been seated in seat 918 of implant 900. Post remover 1400 has a shaft 1402 and a distal end 1404. Distal end 1404 has a bore 1406 with a post engagement surface 1408 that is preferably hex-shaped to cooperatively engage with tool engagement area 1008 of post 1000. Post remover 1400 removes post 1000 from implant 900 by unthreading post 1000 from opening 928 in leading end 904 of implant 900.

Figs. 46-51 show various steps of a preferred method for inserting implant 900 from an anterior approach to the spine and using associated instrumentation disclosed herein.

Figs. 46 and 47 show insertion of a guard 1600 with disc penetrating extensions 1602 into the disc space and the use of drill 700 to prepare the disc space for implantation. Disc penetrating extensions 1602 need not be but are preferably angled to place the adjacent vertebral bodies in angular relationship to each other. As taught in U.S. Patent No. 6,080,155 to Michelson incorporated by reference herein, the guard may have one or more extensions of any size or shape suitable for the intended purpose and one or more bores which could, but need not, be in part overlapping. It is understood that the use of such a guard is only preferred and not required. The guard may be of any type suitable for the purpose of providing protected access while the disc space is prepared and

during implantation including, but not limited to, the guards incorporated by reference above.

In Fig. 48, drill 700 and guard 1600 are withdrawn and driver 1100 is used to insert implant 900 into the prepared disc space. In this example, implant 900 is rotatably inserted so that thread 922 penetrably engages the bone of the adjacent vertebral bodies. At the option of the surgeon, guard 1600 may be left in place throughout the whole procedure, the procedure then being carried out through the hollow shaft of guard 1600. Additionally, implant 900 may be installed without first installing post 1000 into implant 900. However, it is preferred that post 1000 is installed in implant 900 before implant 900 is installed into the disc space.

As illustrated in Fig. 49, radial expander 920 is moved onto post 1000 and implant holder 1200 is moved into position. After flanges 1210 of implant holder 1200 are engaged with arms 909, 910 of implant 900, rotating tool 1300 is inserted through the interior of shaft 1206 so that threaded bore 1302 of rotating tool 1300 cooperatively engages first thread 1004 of post 1000. As shown in Fig. 50, after rotating tool 1300 and post 1000 are rotationally engaged, continued rotation of rotating tool 1300 linearly forces radial expander 920 away from trailing end 902 and to bear against the interior surfaces of arms 909, 910, causing arms 909, 910 to be forced away from the mid-longitudinal axis of the implant as described above in relation to implant 100 and Figs. 9-11.

As shown in Fig. 51, after radial expander 920 is seated into seat 918 and implant 900 is placed in an expanded state, post remover 1400 is used to engage head 1006 of post 1000. Rotating post remover 1400 disengages post 1000 from threaded opening 928 of implant 900, allowing post 1000 to be withdrawn through opening 934 of radial expander 920 and from the interior of the implant.

Figs. 52A, 52B, and 53 show two implants 900 in a radially expanded state placed in close proximity to one another within the perimeter of a disc space D. In Fig. 52A and 52B, implants 900 of Fig. 33 are preferably positioned such that shortened arms 909 face the antero-lateral aspect of the vertebral bodies such that the structure of each implant is kept substantially within the disc space to minimize the risk of interference with delicate vascular and neurological structures present adjacent to the disc space. In Fig. 52B, implants 900 are oriented toward each other in a toed-in configuration permitting the implants to be

closer to each other in a side-by-side placement. Such placement permits the use of larger implants to better fill the disc space than may be possible with implants positioned parallel to each other.

In Fig. 53, two implants 900 of Fig. 37, each having opposed shortened arms 909, are preferably placed such that the mid-longitudinal axis of each implant are in closer proximity to one another than the embodiment shown in Fig. 52A. Closer placement is made possible, by way of example only, by positioning each implant such that shortened arms 909 face each other within the disc space. Additionally, the size of thread 922 may be reduced towards trailing end 902 so that trailing end 902 has a reduced thread portion 923 to minimize contact with the thread of an adjacent implant. Such an orientation permits greater expansion to occur without a lengthened arm from one implant crossing the lengthened arm of an implant adjacent thereto. In all the embodiments described herein, it should be apparent that a number of arrangements of shortened and/or lengthened arms are possible and all within the broad scope of the present invention.

Figs. 54-56 show a preferred remover and methods of disengaging radial expander 920 from seat 918 of implant 900 if it is desired to uninstall implant 900. Fig. 54 shows a remover 1500 for removing radial expander 920 from hollow interior 903 of implant 900 through trailing end 902. Remover 1500 has a shaft 1502 and a distal end 1504. Distal end 1504 has a bore 1514 with a thread 1516 that is configured for cooperative engagement with first thread 1004 of post 1000, a collar 1518 with an outer diameter slightly smaller than the diameter of hollow interior 903 of implant 900 in a radially expanded state, and a bearing 1520 that allows remover 1500 to rotate relative to collar 1518. Bore 1514 preferably has an unthreaded portion at its leading end that permits remover 1500 to move over a portion of post 1000 prior to rotational engagement.

As shown in Figs. 55 and 56, threaded bore 1514 of remover 1500 threads onto post 1000 causing forward movement of remover 1500 into trailing end 904 of implant 900. As remover 1500 moves into trailing end 904, collar 1518 contacts arms 909, 910, forcing arms 909, 910 to move outward away from the mid-longitudinal axis of the implant. This movement in turn causes seat 918 to expand outward to release radial expander 920, thus permitting radial expander 920 to be removed from implant 900.

Fig. 56 shows an instrument, for example a hook 1700, for removing radial expander 920 from implant 900 to return arms 909, 910 to their initial or non-expanded position.

The implants described herein preferably have a generally circular cross section transverse to the mid-longitudinal axis of the implant. In the collapsed position, the implants may have a generally cylindrical configuration or may be in the shape of a cylinder with at least a portion of a side removed. The implants may be tapered from trailing end to leading end and may have a generally frusto-conical configuration in the collapsed position to facilitate insertion into the implantation space.

In another embodiment, in the expanded position, the implants described herein may have a leading end or a trailing end tapered at an angle that matches the angle of the upper, lower, and side portions in the expanded position.

The radially expandable spinal fusion implant may include, be made of, treated, coated, filled, used in combination with, or have a hollow for containing artificial or naturally occurring materials and/or substances suitable for implantation in the human spine. These materials and/or substances include any source of osteogenesis, bone growth promoting materials, bone, bone derived substances or products, demineralized bone matrix, ossifying proteins, bone morphogenetic proteins, hydroxyapatite, genes coding for the production of bone, and bone including, but not limited to, cortical bone. The implant can also be formed of an artificial material stronger than bone such as metal including, but not limited to, titanium and its alloys, surgical grade plastics, plastic composites, ceramics, or other materials suitable for use as a spinal fusion implant. The implant can include at least in part of materials that are bioabsorbable and/or resorbable in the body such as bone and/or bone growth promoting materials. The implant of the present invention can be formed of a porous material or can be formed of a material that intrinsically participates in the growth of bone from one of adjacent vertebral bodies to the other of adjacent vertebral bodies. Where such implants are for posterior implantation, the trailing ends of such implants may be treated with, coated with, or used in combination with chemical substances to inhibit scar tissue formation in the spinal canal. The implants of the present invention may be adapted to facilitate the electrostimulation of the fusion area into which they are inserted and the proximate bone thereabout. The

implant of the present invention may be modified, or used in combination with materials to make it antibacterial, such as, but not limited to, electroplating or plasma spraying with silver ions or other substance. At least a portion of the implant may be treated to promote bone ingrowth between the implant and the adjacent vertebral bodies. The implant of the present invention may be used in combination with spinal fixation hardware, bone screws, plates, rods, tethers of synthetic chords or wires.

Although various embodiments of the present invention have been disclosed, they are but preferred embodiments for the purpose of illustration by example and not limitation. It should be understood that any modifications of these teachings as would be known to one of ordinary skill in the art are anticipated and within the scope of the present inventive teachings.

WHAT IS CLAIMED IS:

1. An interbody spinal fusion implant for implantation from at least in part a posterior approach at least in part within and across the height of a disc space between two adjacent vertebral bodies of an adult human spine, said implant comprising:
  - a body having a leading end for insertion first into the disc space, a trailing end opposite said leading end, and a mid-longitudinal axis along the length of said body, said body having an upper portion adapted to contact one of the adjacent vertebral bodies, a lower portion opposite said upper portion adapted to contact another one of the adjacent vertebral bodies, and at least one side portion between said upper and lower portions, each of said upper, lower, and side portions extending from said trailing end of said body and being spaced apart from one another to form a hollow interior therebetween, said hollow interior being configured to hold at least some bone growth promoting material therein, said upper and lower portions configured to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said body of said implant, each of said upper, lower, and side portions configured to move at least in part in a direction away from the mid-longitudinal axis of the body allowing for expansion of the height and at least a portion of the width of said body, said upper, lower, and side portions having a collapsed position relative to one another allowing for a collapsed height and width of said body and an expanded position relative to one another allowing for an expanded height and width of said body, the expanded height and width of said body being greater than the collapsed height and width of said body, respectively; and
  - an expander at least in part within said hollow interior, said expander configured to cooperatively engage an instrument adapted to be inserted through said trailing end of said body to engage and to move said expander from a position proximate said leading end when said body is in the collapsed position away from said leading end and toward said trailing end of said body to place said body in the expanded position, said expander adapted to contact and to move said upper, lower, and side

portions away from the mid-longitudinal axis of said body, said upper, lower, and side portions of said body adapted to cooperatively engage said expander to locate said expander at a location along the length of said body between and away from each of said leading and trailing ends and to resist dislodgment of said expander from that location when said implant is in use, said expander adapted to hold at least a portion of said upper, lower, and side portions apart so as to maintain the expanded height and width of said body and to resist the collapse of said body to the collapsed body height and width when said body is in the expanded position.

2. The implant of claim 1, wherein said expander includes a threaded opening for threadable engagement with a tool used to move said expander from an initial position to a final position to increase the height and width of said body.
3. The implant of claim 1, wherein said implant in the expanded position has at least one hollow interior portion that is substantially unobstructed by any mechanism to move said expander so as to permit growth of bone from adjacent vertebral body to adjacent vertebral body through said body.
4. The implant of claim 1, wherein each of said upper and lower portions are adapted to cooperate with and to fixedly locate said expander therebetween.
5. The implant of claim 4, wherein each of said upper and lower portions are configured to permit said expander to seat therein in at least said expanded position.
6. The implant of claim 1, wherein said expander has at least one truncated side so as to avoid contact with one of said at least one side portions of said body.
7. The implant of claim 1, wherein said expander is configured to expand the width of said body on one side by contacting only one of said side portions of said body.
8. The implant of claim 1, wherein said expander is configured to receive at least a portion of at least one of said upper, lower, and side portions.
9. The implant of claim 1, wherein at least a portion of said upper, lower, and side portions are separated by a space, said expander includes at least



one guide peg extending therefrom and configured to be placed in said space between at least a portion of at least one of said upper, lower, and side portions.

10. The implant of claim 1, wherein said implant includes only a single expander.
11. The implant of claim 1, wherein at least one of said upper, lower, and side portions comprises a plurality of arms separated from one another at least in part by a space, said space being at least one of an opening, slit, and slot.
12. The implant of claim 11, wherein said space is configured to permit for the growth of bone from vertebral body to vertebral body through said body.
13. The implant of claim 11, wherein said arms are of different lengths.
14. The implant of claim 11, wherein said side portion includes at least one arm having a length less than the length of the arms of said upper and lower portions.
15. The implant of claim 11, wherein said implant includes opposite side portions.
16. The implant of claim 14, wherein said arm having a lesser length provides for a reduced width of said leading end of said body relative to the height of said implant in the expanded position.
17. The implant of claim 11, wherein said arms are aligned parallel with the mid-longitudinal axis of said body in the collapsed position.
18. The implant of claim 1, wherein said implant is at least in part open opposite said side portion.
19. The implant of claim 1, wherein at least one of said upper, lower, and side portions has an interior surface, at least a portion of said interior surface forming a ramp adapted to contact said expander.
20. The implant of claim 1, wherein at least one of said upper, lower, and side portions has an interior surface, at least a portion of said interior surface forming a seat adapted to receive and locate said expander along the length of said body.
21. The implant of claim 1, wherein at least one of said upper, lower, and side portions is sufficiently resilient so as to bend to be moved away from said mid-longitudinal axis of said body.

22. The implant of claim 1, wherein said upper, lower, and side portions when said implant is in the collapsed position form a generally cylindrical shape.
23. The implant of claim 1, wherein said upper, lower, and side portions when said implant is in the expanded position form a generally frusto-conical shape.
24. The implant of claim 1, wherein at least one of said upper, lower, and side portions is at least in part concave along at least portion of the length of said body.
25. The implant of claim 1, further in combination with a post adapted to be inserted at least in part within said hollow interior of said body for moving said expander along at least a portion of the length of said body between said upper and lower portions of said implant.
26. The implant of claim 25, wherein said post has a shaft with a first end adapted to be coupled to one of said leading and trailing ends of said body and a second end opposite said first end configured to cooperatively engage a tool used for inserting said post into said body.
27. The implant of claim 26, wherein said shaft is at least in part threaded and said expander has a threaded opening configured to threadably engage said shaft so that rotation of said post within said body moves said expander along at least a portion of the length of said body to force apart said upper, lower, and side portions.
28. The implant of claim 27, wherein at least a portion of shaft of said post is smooth.
29. The implant of claim 25, wherein said post is configured to pass through at least a portion of at least one of said leading and trailing ends of said body.
30. The implant of claim 1, wherein said trailing end of said body is configured to cooperatively engage a driver for inserting the implant into the implantation space.
31. The implant of claim 1, wherein said trailing end of said body includes at least one non-threaded opening.
32. The implant of claim 1, further comprising a bone engaging surface formed on the exterior of at least said upper and lower portions for engaging the

- adjacent vertebral bodies, said bone engaging surface including at least one of a thread, a ratchet, a spline, surface roughenings, and knurling.
33. The implant of claim 1, wherein said implant comprises an artificial material other than bone.
  34. The implant of claim 1, wherein at least a portion of said upper, lower, and side portions of said implant include a material selected from at least one of titanium, plastic, stainless steel, and carbon fiber.
  35. The implant of claim 1, wherein said implant is made of an artificial material that is stronger than bone.
  36. The implant of claim 1, wherein said implant comprises at least in part of one of bone and bone growth promoting material.
  37. The implant of claim 36, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
  38. The implant of claim 1, in combination with a bone growth promoting material.
  39. The implant of claim 38, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
  40. The implant of claim 1, wherein said implant is treated with a bone growth promoting substance.
  41. The implant of claim 1, wherein said implant is a source of osteogenesis.
  42. The implant of claim 1, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.
  43. The implant of claim 1, wherein said implant is at least in part resorbable.
  44. The implant of claim 1, wherein said implant is formed of a porous material.
  45. The implant of claim 1, in combination with a chemical substance adapted to inhibit scar formation.
  46. The implant of claim 1, in combination with an antimicrobial material.

47. The implant of claim 1, wherein said hollow interior of said implant includes bone growth promoting material selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
48. The implant of claim 1, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.
49. The implant of claim 1, in combination with an implant holder.
50. The implant of claim 1, in combination with an expander driver.
51. The implant of claim 1, in combination with a remover instrument for removing said expander from within said hollow interior of said body.
52. The implant of claim 1, in combination with an instrument for loading bone growth promoting material into at least a portion of the implant.
53. The implant of claim 1, further in combination with at least one of spinal fixation hardware, a bone screw, a plate, a rod, a tether of synthetic chord, and a tether of wire.
54. An interbody spinal fusion implant for implantation from at least in part an anterior approach at least in part within and across the height of a disc space between two adjacent vertebral bodies of an adult human spine, said implant comprising:
  - a body having a leading end for insertion first into the disc space, a trailing end opposite said leading end, and a mid-longitudinal axis along the length of said body, said body having a base proximate said leading end, an upper portion adapted to contact one of the adjacent vertebral bodies, a lower portion opposite said upper portion adapted to contact another one of the adjacent vertebral bodies, and at least one side portion between said upper and lower portions, each of said upper, lower, and side portions extending from said base of said body and being spaced apart from one another to form a hollow interior therebetween, said hollow interior being configured to hold at least some bone growth promoting material therein, said upper and lower portions configured to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said body of said implant, each of said upper, lower, and side

portions configured to move at least in part in a direction away from the mid-longitudinal axis of said body allowing for expansion of the height and at least a portion of the width of said body, said upper, lower, and side portions having a collapsed position relative to one another allowing for a collapsed height and width of said body and an expanded position relative to one another allowing for an expanded height and width of said body, the expanded height and width of said body being greater than the collapsed height and width of said body, respectively; and

an expander at least in part within said hollow interior, said expander configured to contact an instrument adapted to be inserted through said trailing end of said body to move said expander from a position proximate said trailing end when said body is in the collapsed position away from said trailing end and toward said base of said body to place said body in the expanded position, said expander adapted to contact and to move said upper, lower, and side portions away from the mid-longitudinal axis of said body, said upper, lower, and side portions of said body adapted to cooperatively engage said expander to locate said expander at a location along the length of said body between and away from each of said leading and trailing ends and to resist dislodgment of said expander from that location when said implant is in use, said expander adapted to hold at least a portion of said upper, lower, and side portions apart so as to maintain the expanded height and width of said body and to resist the collapse of said body to the collapsed body height and width when said body is in the expanded position.

55. The implant of claim 54, wherein said expander is adapted to cooperatively engage a tool used to move said expander from an initial position to a final position to increase the height and width of said body.
56. The implant of claim 54, wherein said expander includes a threaded opening for threadable engagement with a tool used to move said expander from an initial position to a final position to increase the height and width of said body.
57. The implant of claim 54, wherein said implant in the expanded position has at least one hollow interior portion that is substantially unobstructed by any

- mechanism to move said expander so as to permit growth of bone from adjacent vertebral body to adjacent vertebral body through said body.
58. The implant of claim 54, wherein each of said upper and lower portions are adapted to cooperate with and to fixedly locate said expander therebetween.
59. The implant of claim 58, wherein each of said upper and lower portions are configured to permit said expander to seat therein in at least said expanded position.
60. The implant of claim 54, wherein said expander has at least one truncated side so as to avoid contact with one of said at least one side portions of said body.
61. The implant of claim 54, wherein said expander is configured to expand the width of said body on one side by contacting only one of said side portions of said body.
62. The implant of claim 54, wherein said expander is configured to receive at least a portion of at least one of said upper, lower, and side portions.
63. The implant of claim 54, wherein at least a portion of said upper, lower, and side portions are separated by a space, said expander includes at least one guide peg extending therefrom and configured to be placed in said space between at least a portion of at least one of said upper, lower, and side portions.
64. The implant of claim 54, wherein said implant includes only a single expander.
65. The implant of claim 54, wherein at least one of said upper, lower, and side portions comprises a plurality of arms separated from one another at least in part by a space, said space being at least one of an opening, slit, and slot.
66. The implant of claim 65, wherein said space is configured to permit for the growth of bone from vertebral body to vertebral body through said body.
67. The implant of claim 65, wherein said arms are of different lengths.
68. The implant of claim 65, wherein said side portion includes at least one arm having a length less than the length of the arms of said upper and lower portions.

69. The implant of claim 65, wherein said implant includes opposite side portions.
70. The implant of claim 67, wherein said arm having a lesser length provides for a reduced width of said trailing end of said body relative to said height of said implant in the expanded position.
71. The implant of claim 65, wherein said arms are aligned parallel with the mid-longitudinal axis of said body in the collapsed position.
72. The implant of claim 54, wherein said implant is at least in part open opposite said side portion.
73. The implant of claim 54, wherein at least one of said upper, lower, and side portions has an interior surface, at least a portion of said interior surface forming a ramp adapted to contact said expander.
74. The implant of claim 54, wherein at least one of said upper, lower, and side portions has an interior surface, at least a portion of said interior surface forming a seat adapted to receive and locate said expander along the length of said body.
75. The implant of claim 54, wherein at least one of said upper, lower, and side portions is sufficiently resilient so as to bend to be moved away from said mid-longitudinal axis of said body.
76. The implant of claim 54, wherein said upper, lower, and side portions when said implant is in the collapsed position form a generally cylindrical shape.
77. The implant of claim 54, wherein said upper, lower, and side portions when said implant is in the expanded position form a generally frusto-conical shape.
78. The implant of claim 54, wherein at least one of said upper, lower, and side portions is at least in part concave along at least a portion of the length of said body.
79. The implant of claim 54, further in combination with a post adapted to be inserted at least in part within said hollow interior of said body for moving said expander along at least a portion of the length of said body between said upper and lower portions of said implant.
80. The implant of claim 79, wherein said post has a shaft with a first end adapted to be coupled to one of said leading and trailing ends of said body

and a second end opposite said first end configured to cooperatively engage a tool used for inserting said post into said body.

81. The implant of claim 80, wherein said shaft is at least in part threaded and said expander has a threaded opening configured to threadably engage said shaft so that rotation of said post within said body moves said expander along at least a portion of the length of said body to force apart said upper, lower, and side portions.
82. The implant of claim 81, wherein at least a portion of shaft of said post is smooth.
83. The implant of claim 79, wherein said post is configured to pass through at least a portion of at least one of said leading and trailing ends of said body.
84. The implant of claim 54, wherein said trailing end of said body is configured to cooperatively engage a driver for inserting the implant into the implantation space.
85. The implant of claim 54, wherein said trailing end of said body includes at least one non-threaded opening.
86. The implant of claim 54, further comprising a bone engaging surface formed on the exterior of at least said upper and lower portions for engaging the adjacent vertebral bodies, said bone engaging surface including at least one of a thread, a ratchet, a spline, surface roughenings, and knurling.
87. The implant of claim 54, wherein said implant comprises an artificial material other than bone.
88. The implant of claim 54, wherein at least a portion of said upper, lower, and side portions of said implant include a material selected from at least one of titanium, plastic, stainless steel, and carbon fiber.
89. The implant of claim 54, wherein said implant is made of an artificial material that is stronger than bone.
90. The implant of claim 54, wherein said implant comprises at least in part of one of bone and bone growth promoting material.
91. The implant of claim 90, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone



- matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
92. The implant of claim 54, in combination with a bone growth promoting material.
  93. The implant of claim 92, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
  94. The implant of claim 54, wherein said implant is treated with a bone growth promoting substance.
  95. The implant of claim 54, wherein said implant is a source of osteogenesis.
  96. The implant of claim 54, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.
  97. The implant of claim 54, wherein said implant is at least in part resorbable.
  98. The implant of claim 54, wherein said implant is formed of a porous material.
  99. The implant of claim 54, in combination with a chemical substance adapted to inhibit scar formation.
  100. The implant of claim 54, in combination with an antimicrobial material.
  101. The implant of claim 54, wherein said hollow interior of said implant includes bone growth promoting material selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
  102. The implant of claim 54, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.
  103. The implant of claim 54, in combination with an implant holder.
  104. The implant of claim 54, in combination with an expander driver.
  105. The implant of claim 54, in combination with a remover instrument for removing said expander from within said hollow interior of said body.
  106. The implant of claim 54, in combination with an instrument for loading bone growth promoting material into at least a portion of the implant.

107. The implant of claim 54, further in combination with at least one of spinal fixation hardware, a bone screw, a plate, a rod, a tether of synthetic chord, and a tether of wire.
108. An apparatus for inserting at least in part within and across the height of a disc space between two adjacent vertebral bodies of the human spine a spinal implant having upper and lower portions, and an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position, said apparatus comprising:
- an inserter guide having a leading end and a trailing end, said leading end of said inserter guide being configured to cooperatively engage the trailing end of the implant, said inserter guide having a hollow interior forming a passage from said trailing end to said leading end through said inserter guide;
  - a post adapted to be inserted at least in part through the trailing end of the implant and into a hollow interior of the implant for moving the expander along at least a portion of the length of the implant between the upper and lower portions of the implant, said post having a leading end configured to cooperatively engage the expander and a trailing end adapted to be coupled to the implant and cooperatively engage an instrument for moving said post; and
  - an inner shaft configured to be inserted at least in part within said passage of said inserter guide, said inner shaft having a leading end and a trailing end, said leading end of said inner shaft being configured to cooperatively engage the trailing end of said post, said inner shaft adapted to move said post so as to move the expander toward the trailing end of the implant to expand the height and at least a portion of the width of the implant.
109. The apparatus of claim 108, wherein said leading end of said inserter guide includes an implant engaging head to cooperatively engage the implant to hold and manipulate the implant during insertion of the implant into the disc space.
110. The apparatus of claim 109, wherein said implant engaging head includes at least one of a flange and a pin.

111. The apparatus of claim 108, wherein said inserter guide further comprises a handle proximate said trailing end of said inserter guide.
112. The apparatus of claim 108, wherein said trailing end of said inserter guide is funnel-shaped to facilitate the introduction of bone growth promoting material through said passage of said inserter guide and into at least a portion of the spinal implant.
113. The apparatus of claim 108, wherein said inserter guide is configured to be inserted at least in part within a guard for providing protected access to the disc space and the adjacent vertebral bodies.
114. The apparatus of claim 108, further in combination with a guard for providing protected access to the disc space and the adjacent vertebral bodies.
115. The apparatus of claim 108, wherein said inner shaft is adapted to rotate within said inserter guide to rotate said post and move the expander toward the trailing end of the implant to expand the height and at least a portion of the width of the implant.
116. The apparatus of claim 108, wherein said leading end of said inner shaft is adapted hold said post such that upon disengagement of said post from the implant said inner shaft withdraws said post through said inserter guide.
117. The apparatus of claim 117, wherein said leading end of said inner shaft includes at least one of a detent and a spring flange.
118. The apparatus of claim 117, wherein said leading end of said inner shaft forms an interference fit with said post.
119. The apparatus of claim 108, wherein said trailing end of said inner shaft is configured to cooperatively engage a device for rotating said inner shaft.
120. The apparatus of claim 108, further comprising a plunger configured to be inserted at least in part within said passage of said inserter guide, said plunger adapted to advance bone growth promoting material through said passage of said inserter guide and into at least a portion of the implant.
121. The apparatus of claim 120, wherein said plunger has an outer shaft and an inner rod at least in part within said outer shaft in slideable relationship to said outer shaft.

122. The apparatus of claim 121 wherein said outer shaft has a leading end for insertion first into said inserter guide and a trailing end opposite said leading end, said plunger being configured to limit the extension of said inner rod from the leading end of said outer shaft.
123. The apparatus of claim 122, further comprising a clamp having a tightened position for holding said inner rod in fixed relationship to said outer shaft of said plunger and a released position for permitting travel of said inner rod beyond said leading end of said outer shaft of said plunger.
124. The apparatus of claim 123, further comprising a stop to limit travel of said inner rod relative to said outer shaft of said plunger.
125. The apparatus of claim 124, wherein at least a portion of said plunger is configured to extend beyond the leading end of said inserter guide and at least in part within the spinal implant.
126. An apparatus for use with a spinal implant having an expander for expanding the height of the implant from a collapsed position to an expanded position, the implant having a leading end for insertion first into a disc space between two adjacent vertebral bodies of the human spine and a trailing end opposite said leading end, the implant having at least upper and lower portions adapted to be moved away from one another by the expander when positioned therebetween, said apparatus comprising:
  - an elongated shaft having a leading end and a trailing end opposite said leading end, and a mid-longitudinal axis;
  - an enlarged head proximate said leading end of said shaft configured to be inserted at least in part between the upper and lower portions of the implant, said enlarged head adapted to move apart the upper and lower portions to release the expander therebetween; and
  - a projection extending from said enlarged head adapted to cooperatively engage the expander for removal of the expander from within the implant.
127. The apparatus of claim 126, wherein said projection is a threaded rod configured to threadably engage an opening in the expander.
128. The apparatus of claim 126, wherein said trailing end of said shaft is adapted to cooperatively engage a handle.

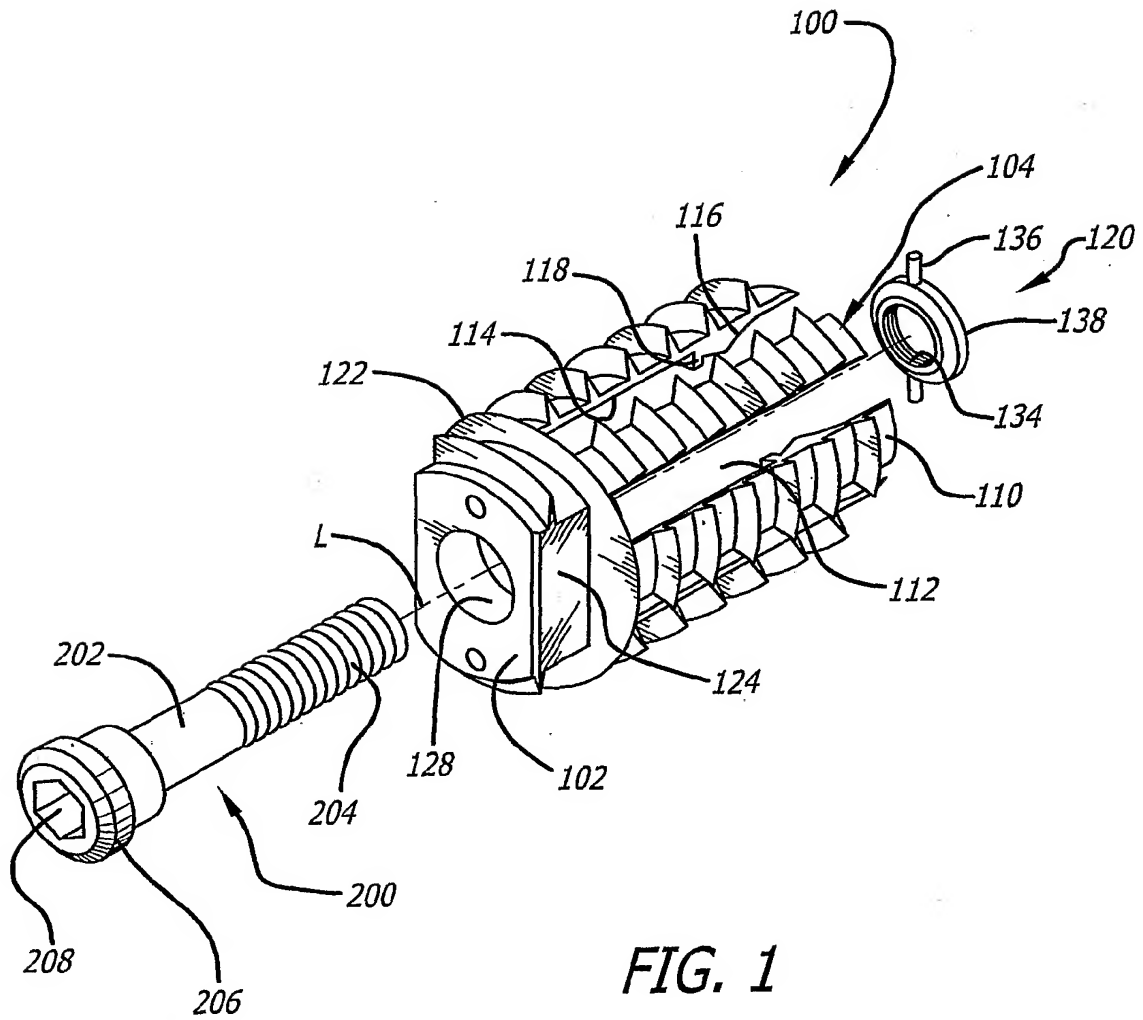
129. An apparatus for inserting at least in part within and across the height of a disc space between two adjacent vertebral bodies of the human spine a spinal implant having an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position, the implant having upper, lower, and side portions comprising a plurality of arms separated by spaces, said apparatus comprising:
- an inserter having a leading end and a trailing end opposite said leading end, said leading end of said inserter guide having a plurality of spaced apart portions, said spaced apart portions of said inserter configured to fit in the spaces between the arms of the spinal implant to cooperatively engage said inserter to the implant.
130. The apparatus of claim 129, wherein at least a portion of said leading end of said inserter has a hollow interior.
131. The apparatus of claim 129, wherein said leading end includes a longitudinal bore extending into at least a portion of said inserter.
132. The apparatus of claim 129, wherein at least a portion of said leading end of said inserter is tapered to facilitate insertion between the arms of the implant.
133. An apparatus for holding a spinal implant having an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position, the implant having upper, lower, and side portions comprising a plurality of arms separated by spaces, said apparatus comprising:
- a sleeve having a leading end and a trailing end and a passageway from said trailing end to said leading end, said passageway providing access to the implant through said sleeve, said leading end of said sleeve having a plurality of spaced apart portions, said spaced apart portions of said sleeve configured to fit in the spaces between the arms of the spinal implant to cooperatively engage said sleeve to the implant.
134. The apparatus of claim 133, further comprising a handle proximate said trailing end of said sleeve.
135. The apparatus of claim 133, wherein said spaced apart portions of said sleeve are flexible at least in part.

136. An apparatus for use with a spinal implant having an expander for expanding the height of the implant from a collapsed position to an expanded position, the implant having a leading end for insertion first into a disc space between two adjacent vertebral bodies of the human spine and a trailing end opposite said leading end, the implant having at least upper and lower portions adapted to be moved away from one another by the expander when positioned therebetween, said apparatus comprising:

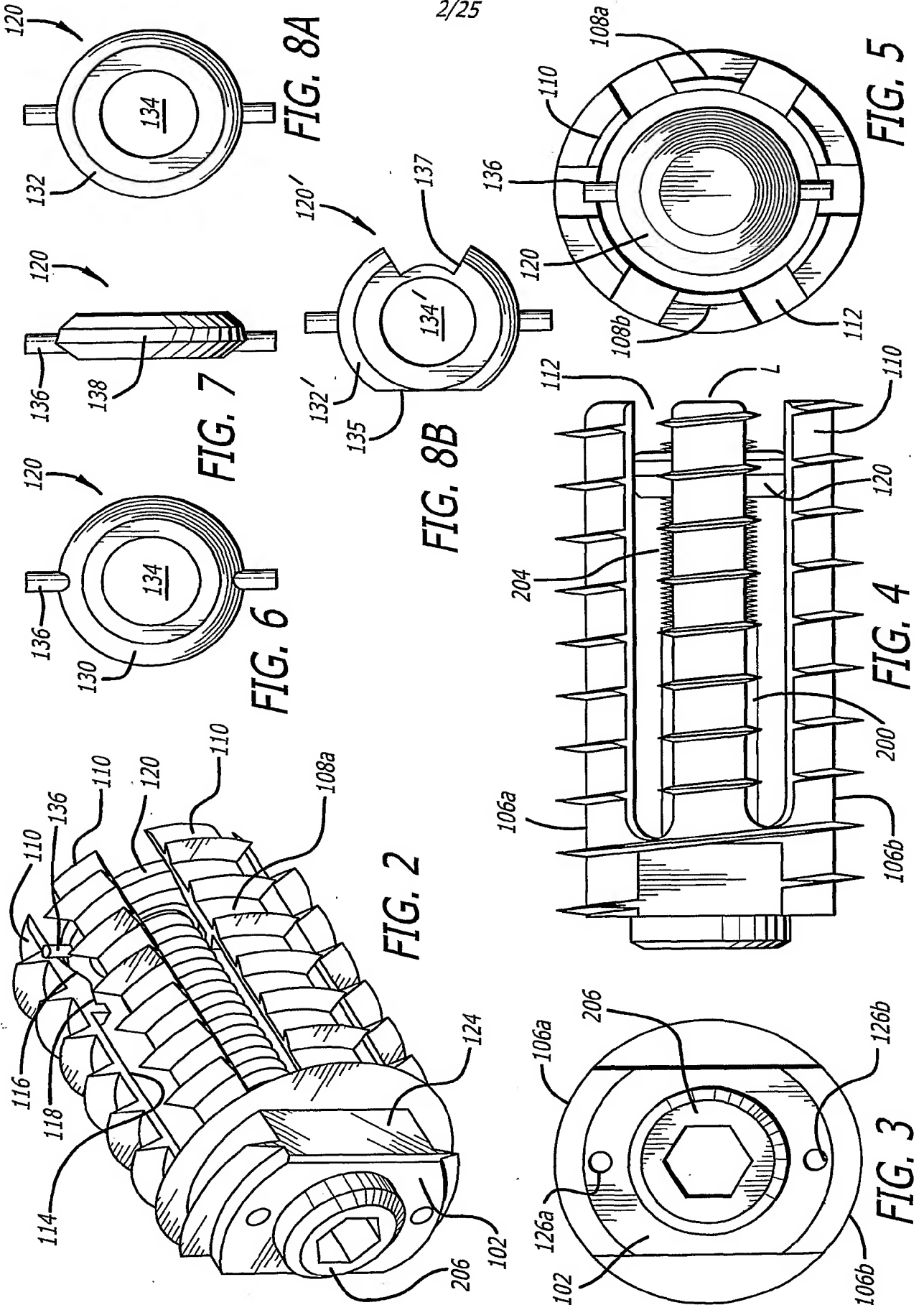
an elongated shaft having a mid-longitudinal axis, a leading end, and a trailing end opposite said leading end, said leading end having a bore therein and an enlarged head with a collar in movable relationship to said head that permits rotational movement of said head independent of said collar, said collar and said head being configured to be inserted at least in part between the upper and lower portions of the implant, said collar adapted to bear against and move apart the upper and lower portions of the implant to release the expander therebetween; and

a post adapted to be inserted at least in part through the trailing end of the spinal implant for guiding the elongated shaft along the mid-longitudinal axis between the upper and lower portions of said implant, said post having a leading end configured to cooperatively engage the implant and a trailing end adapted to be received within said bore of said elongated shaft, said head of said elongated shaft adapted to rotate about said post.

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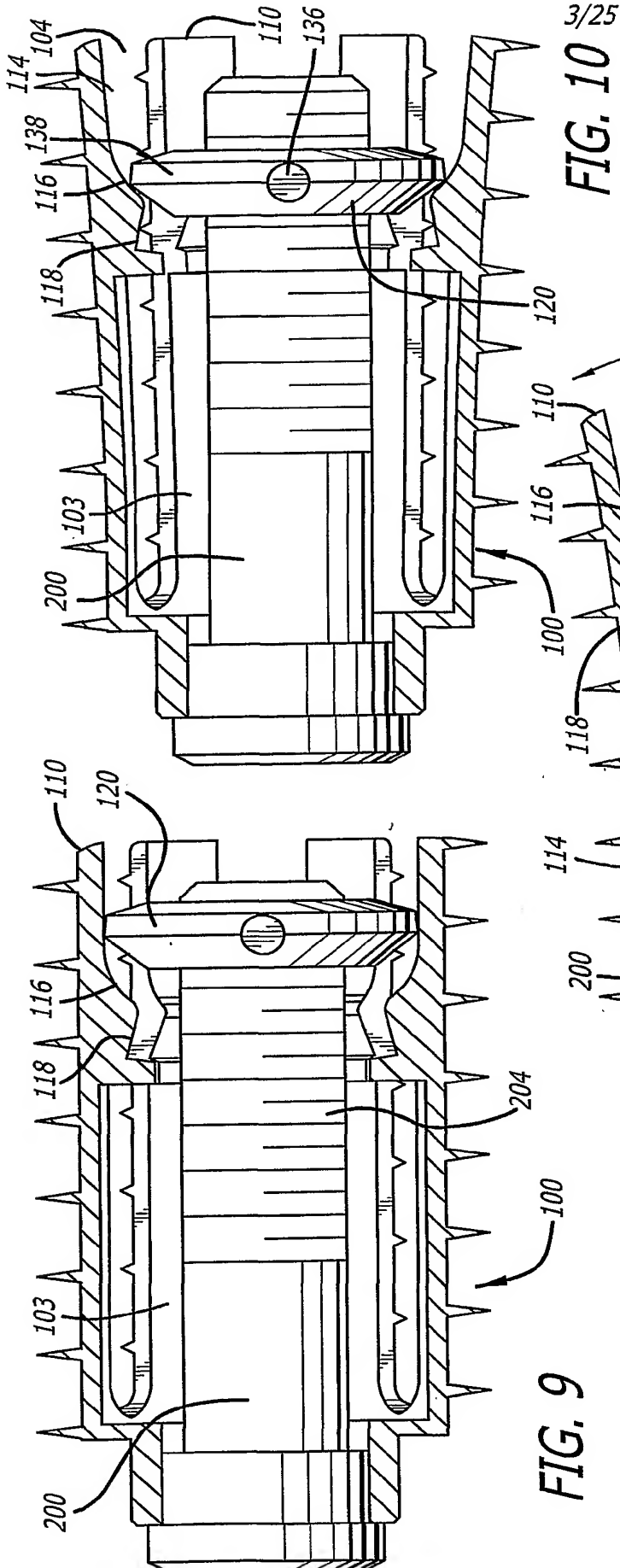
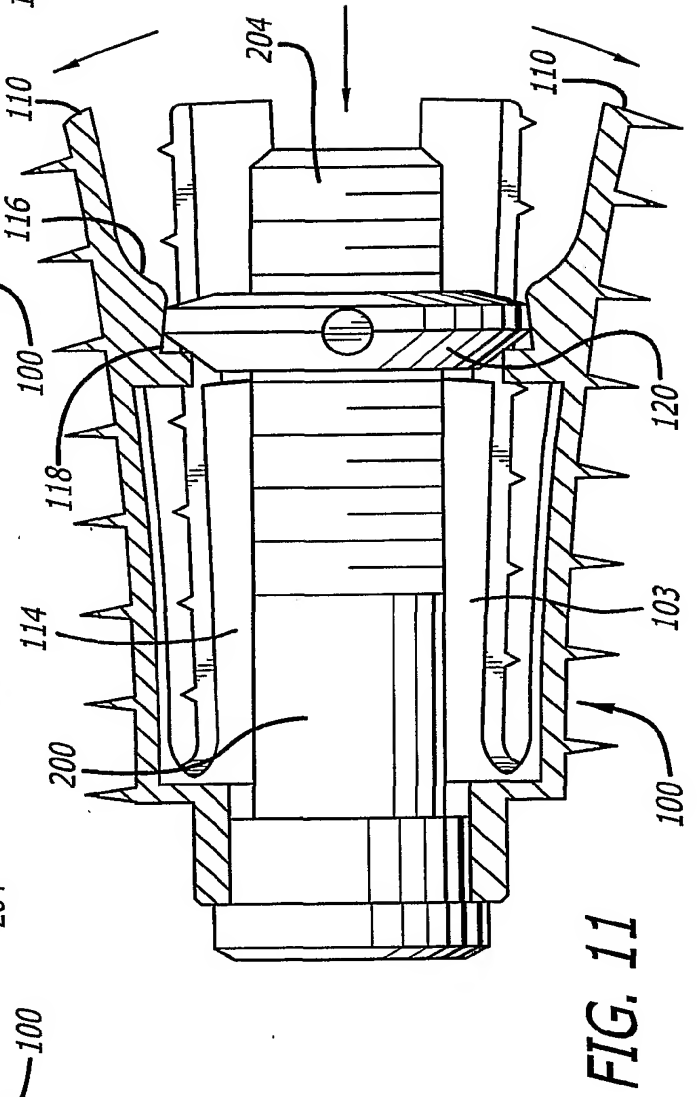
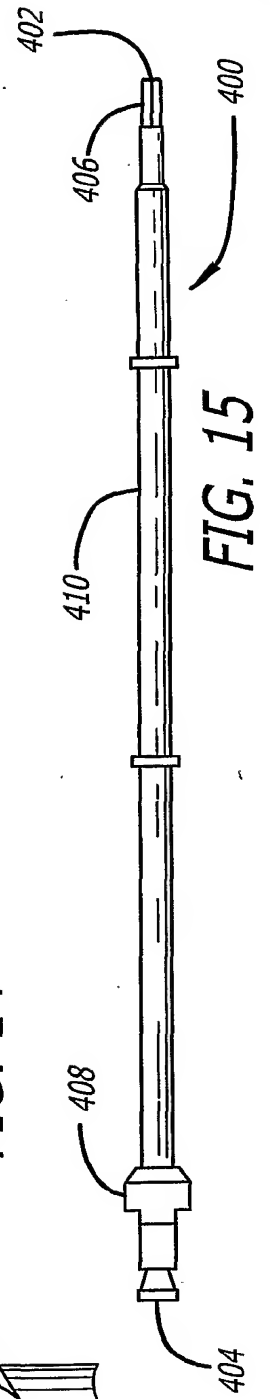
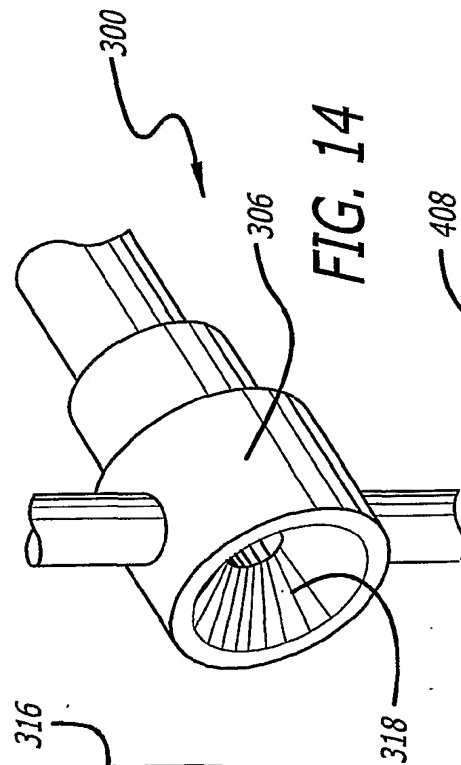
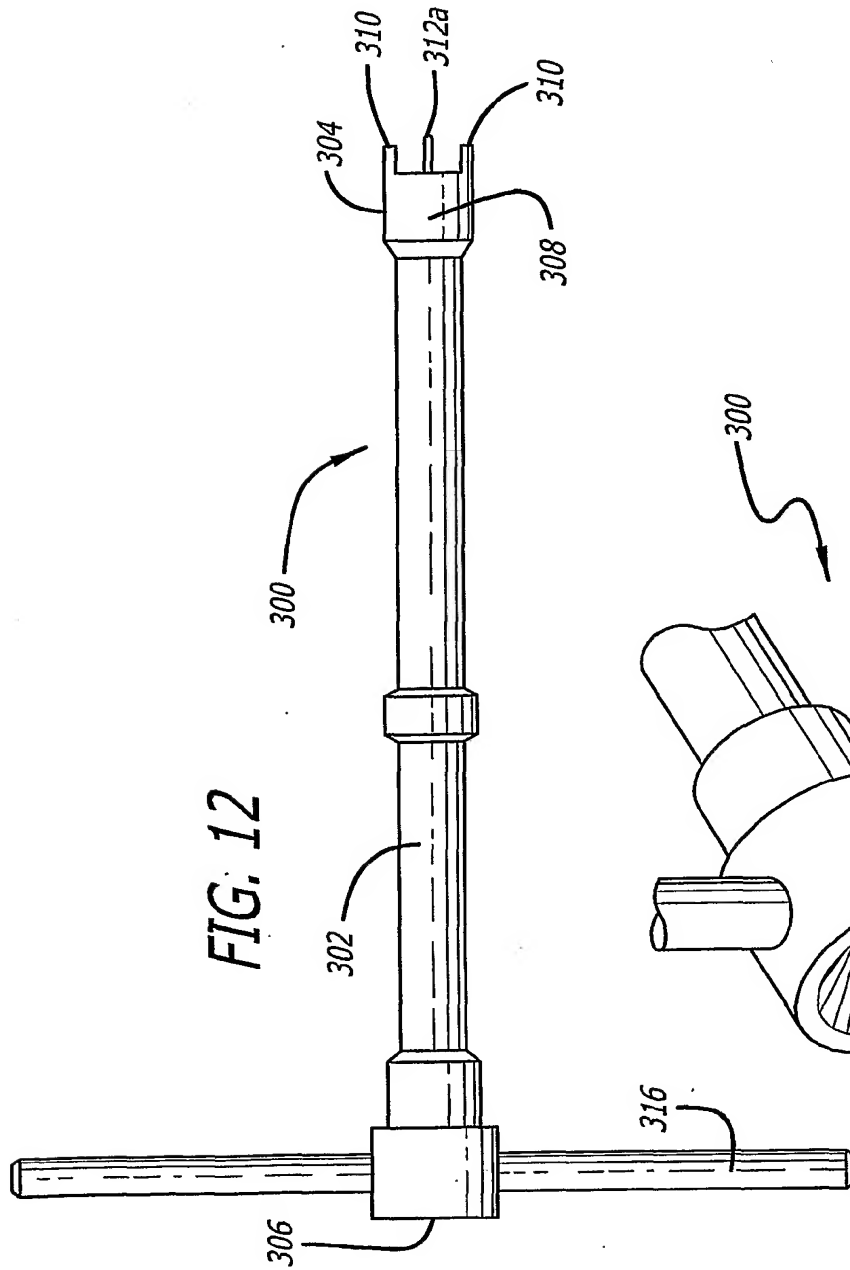
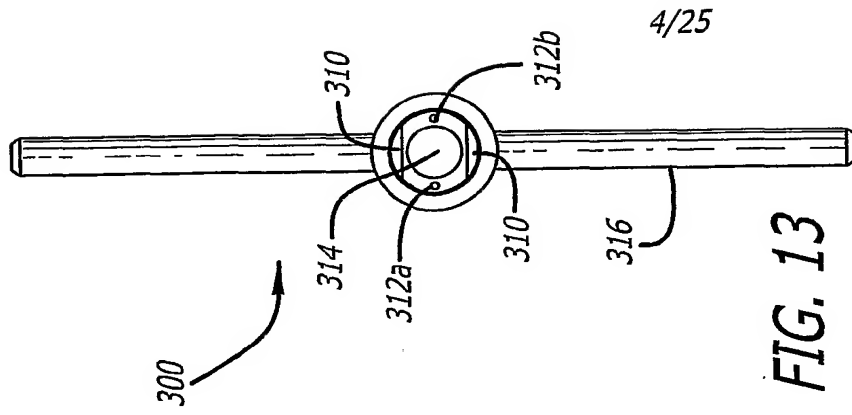


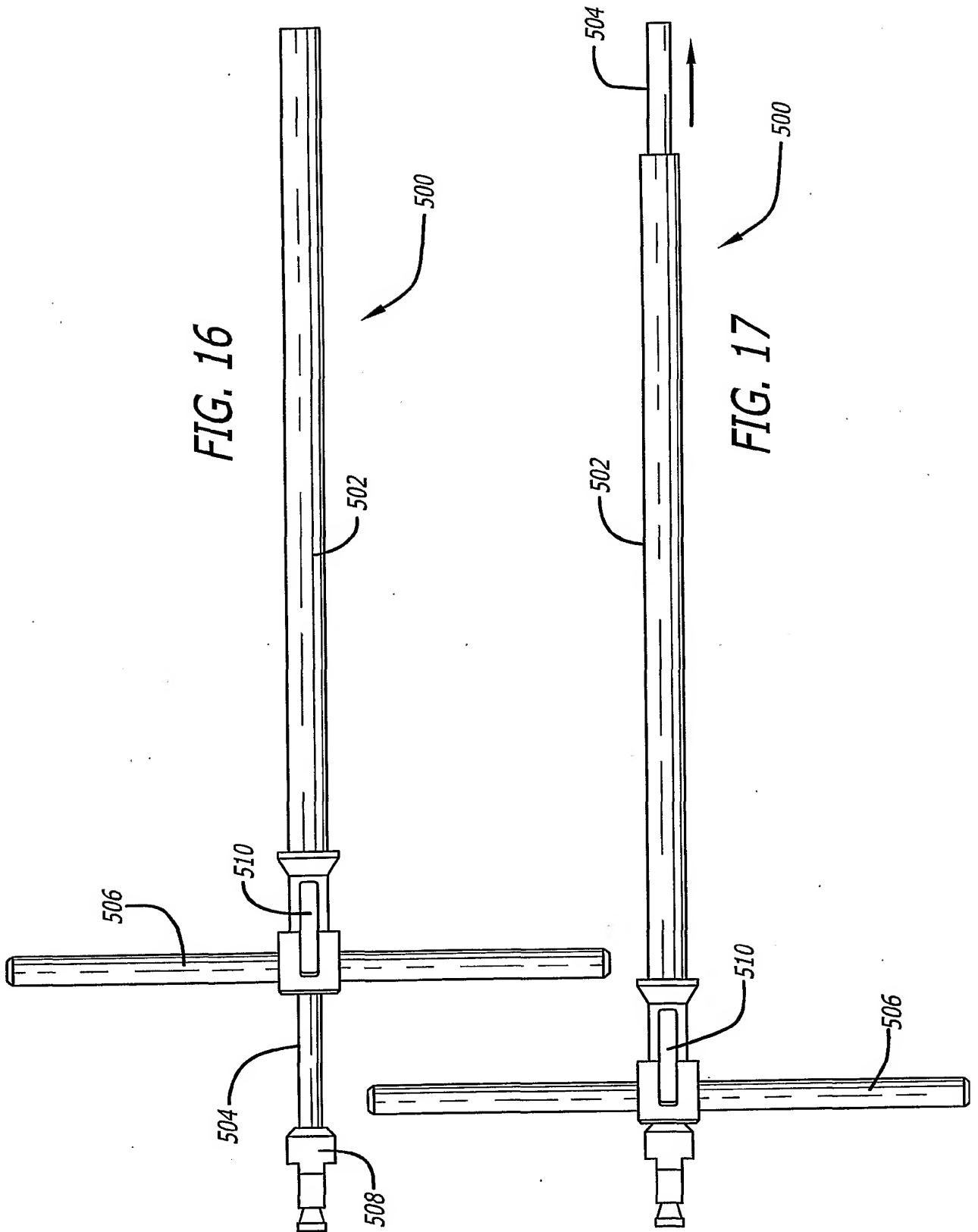
FIG. 9

FIG. 10





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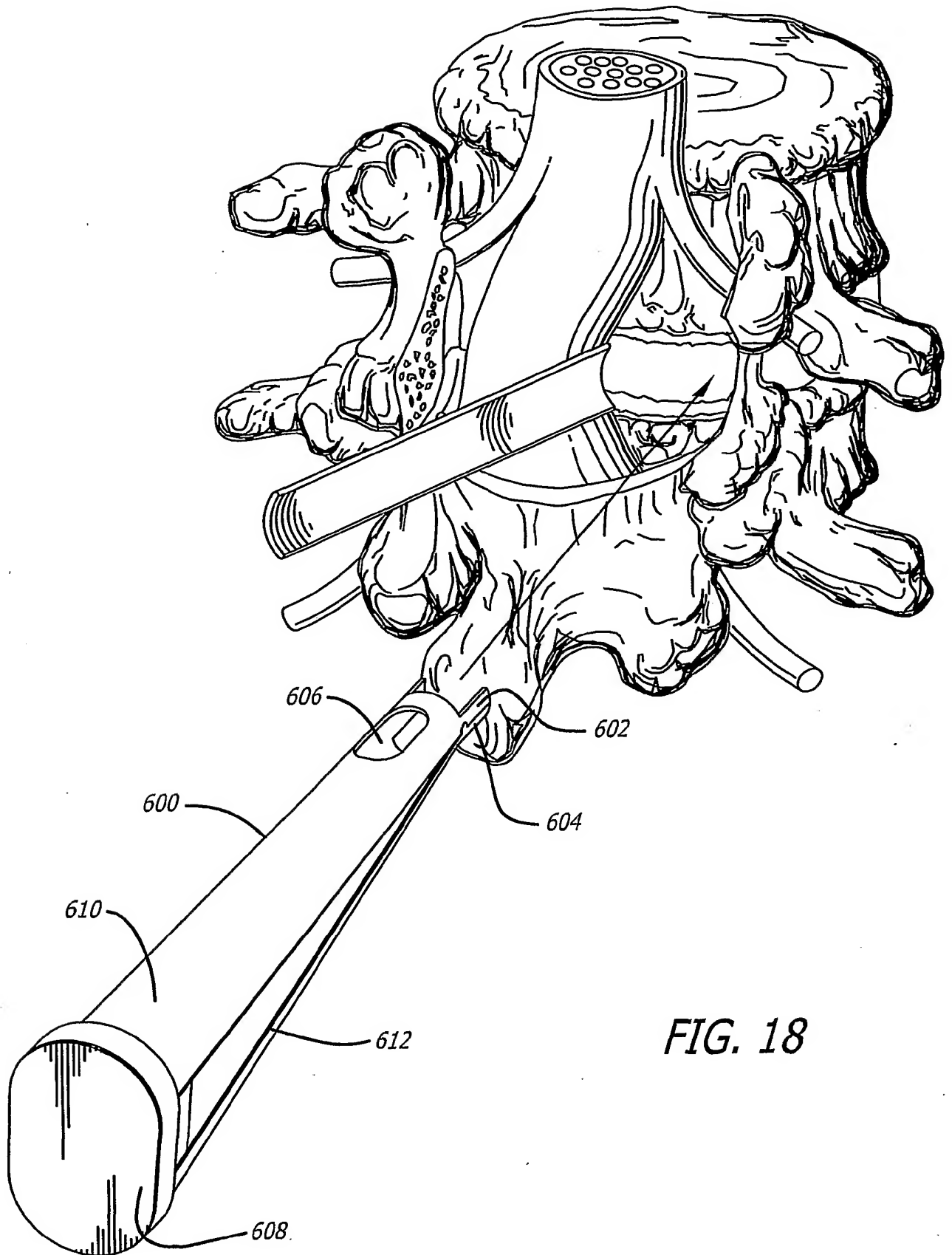
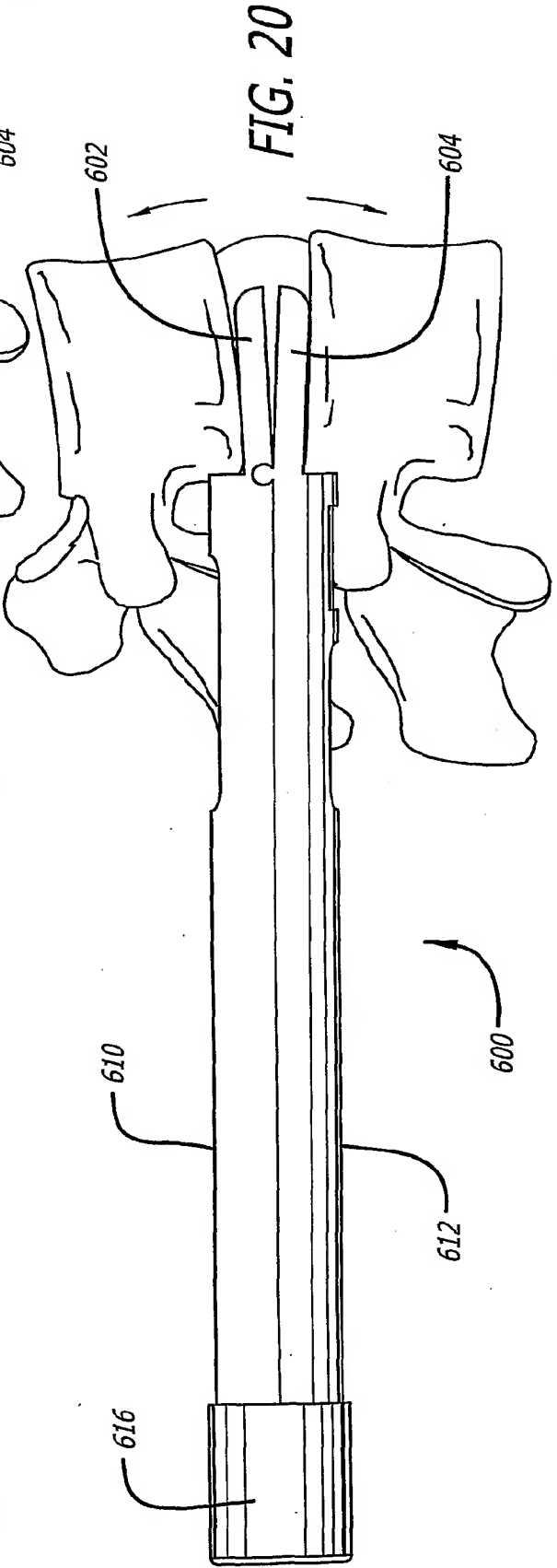
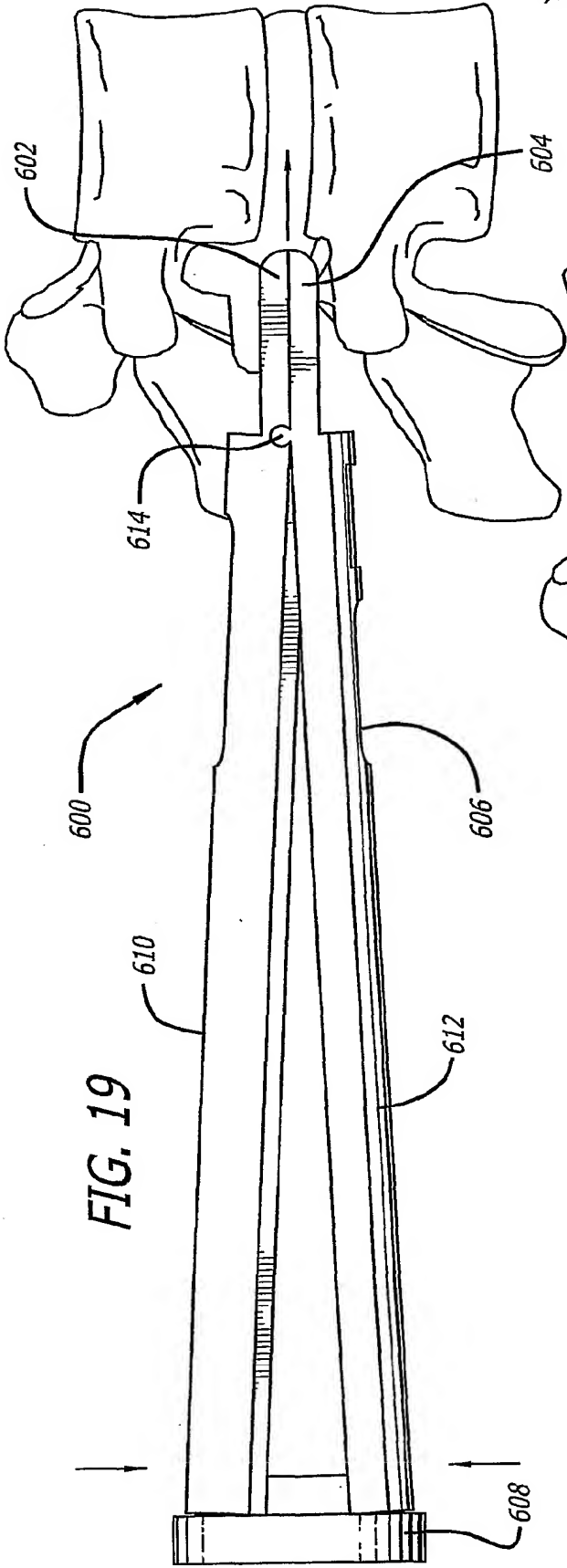


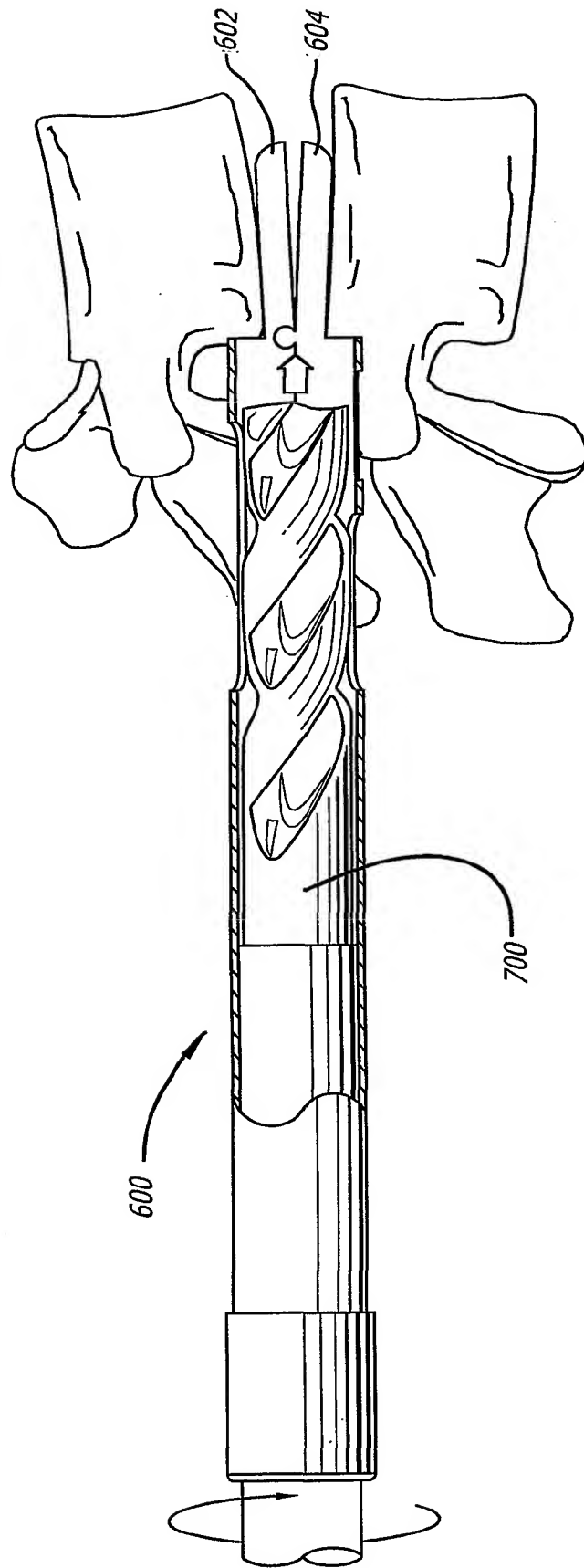
FIG. 18

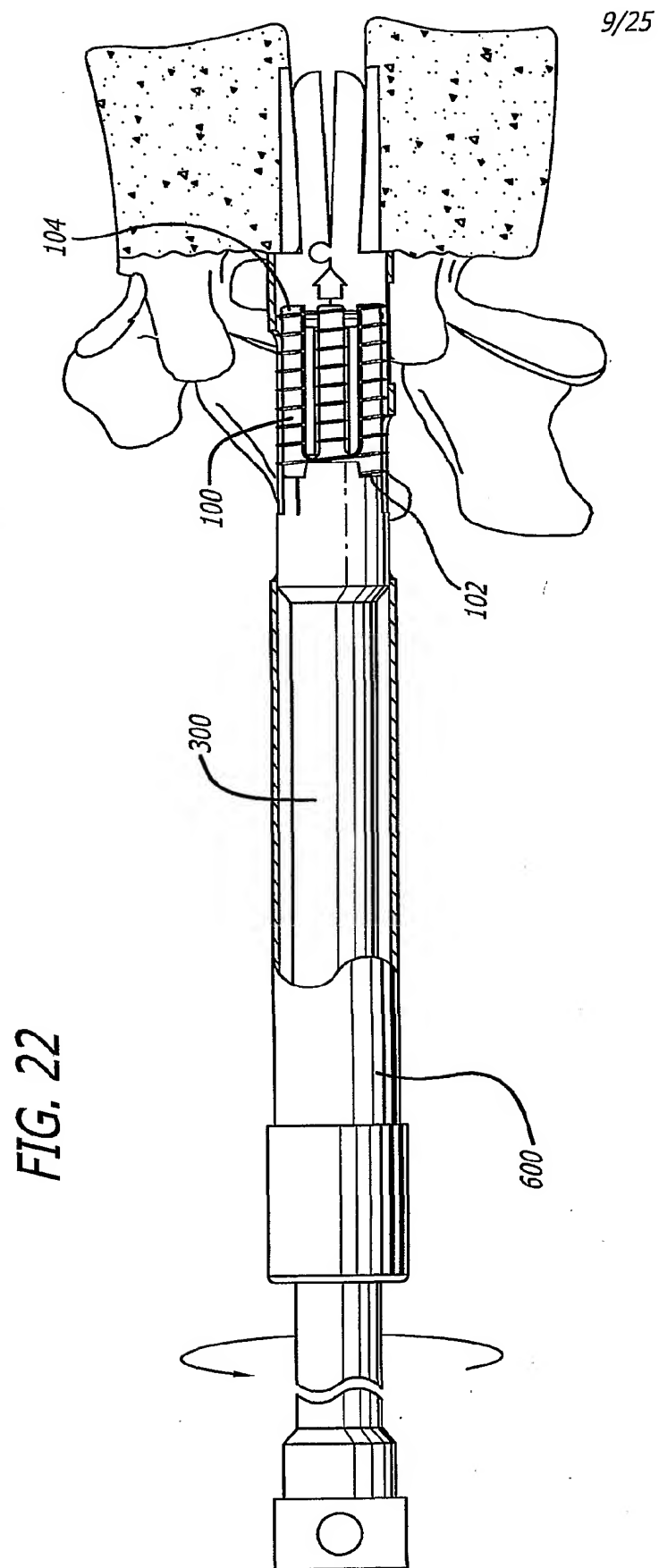
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FIG. 21





**FIG. 23**

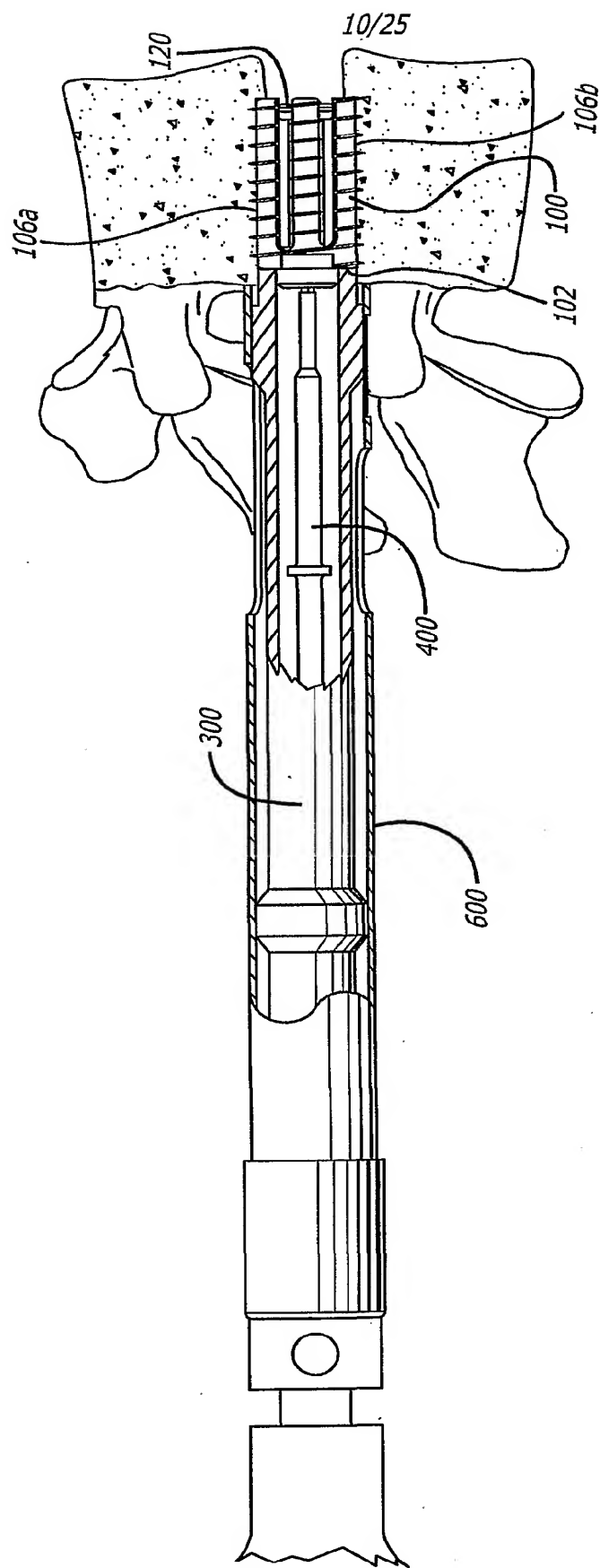
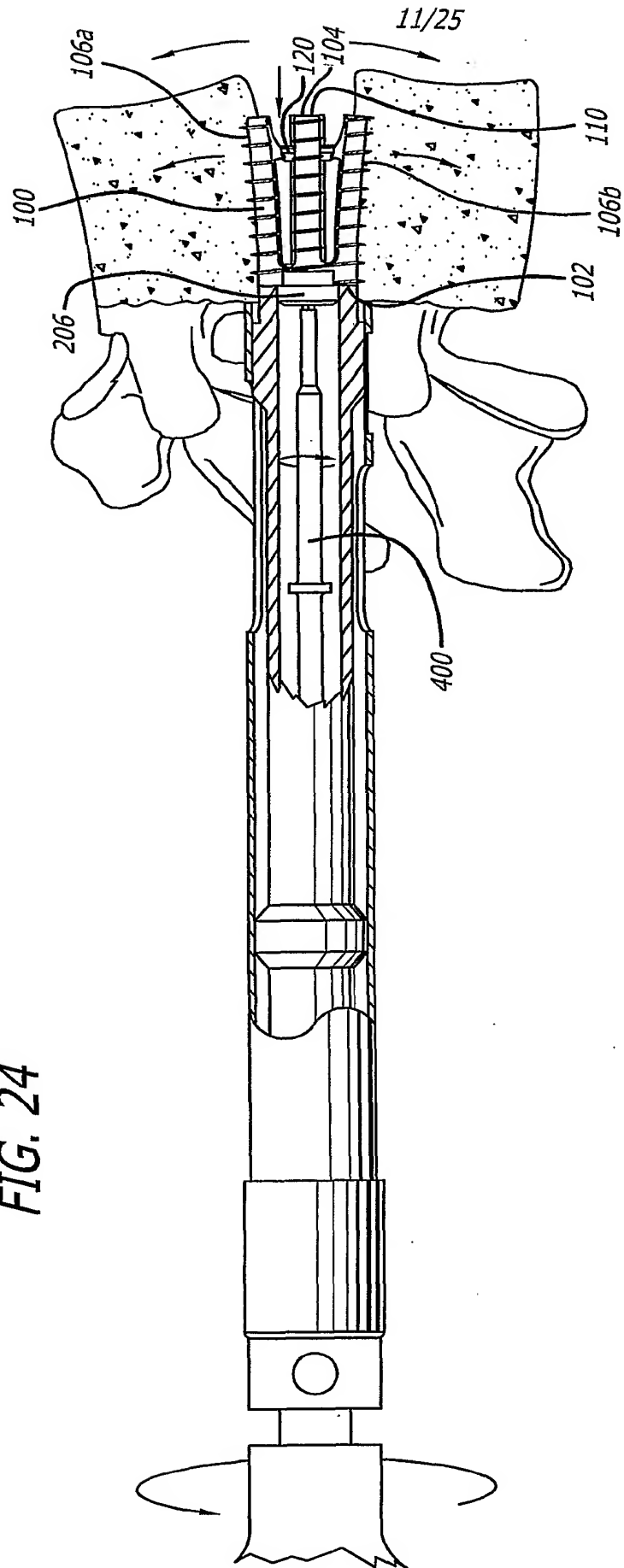
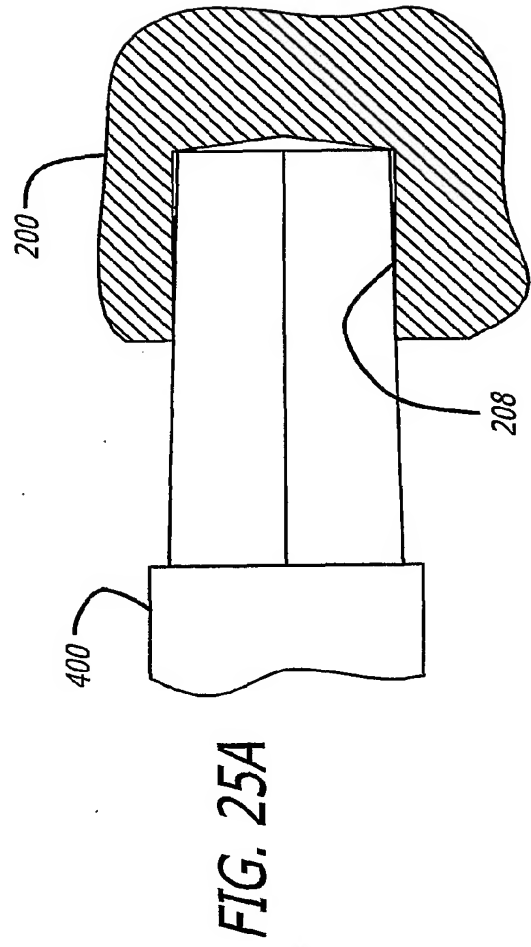
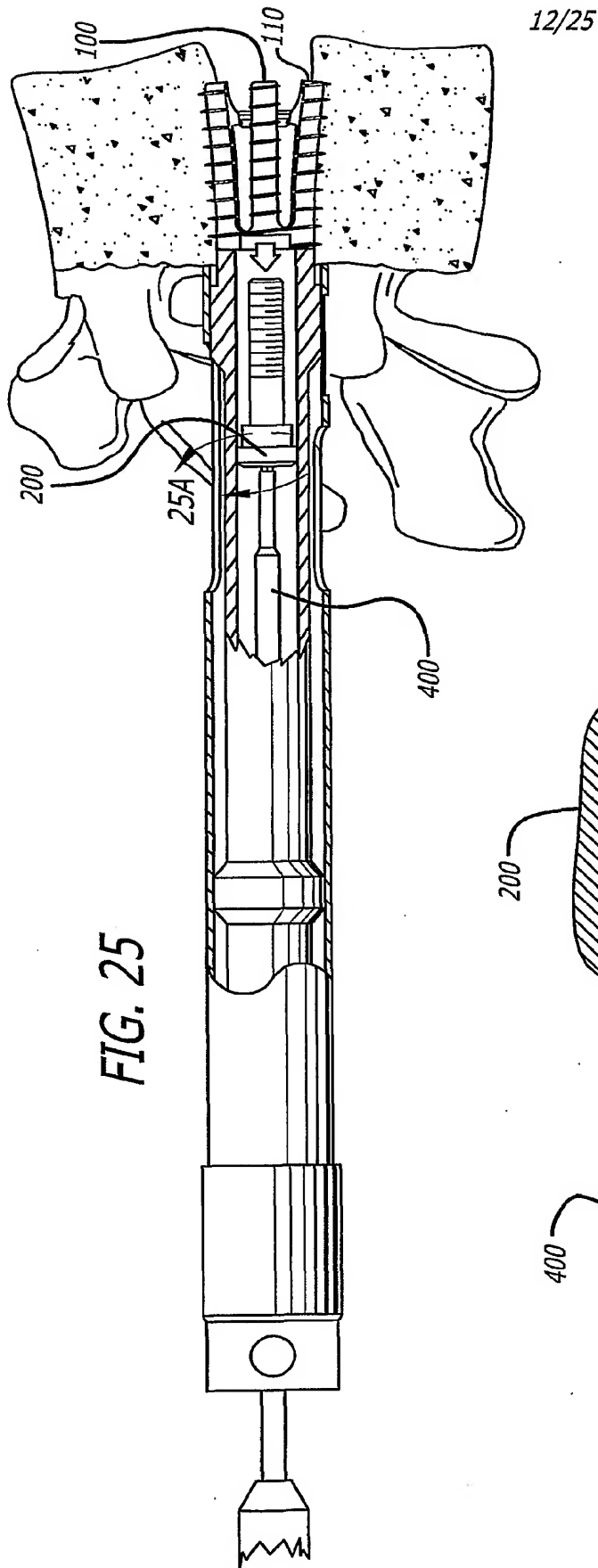
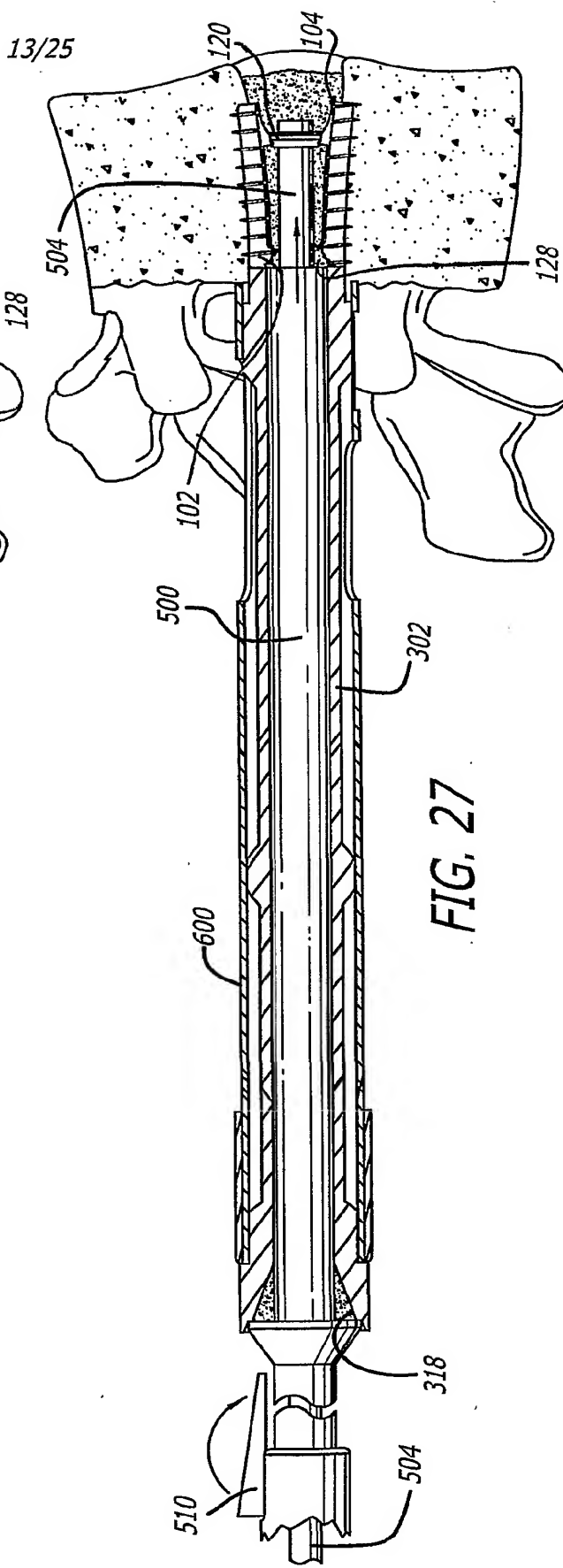
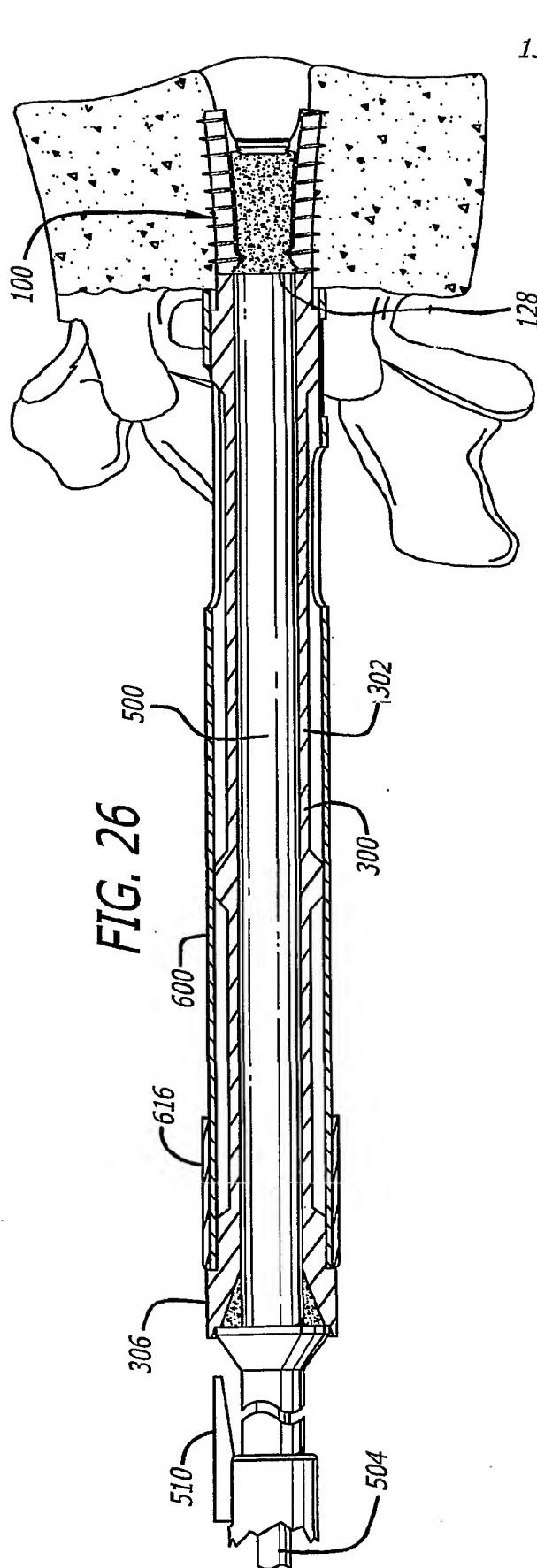




FIG. 24







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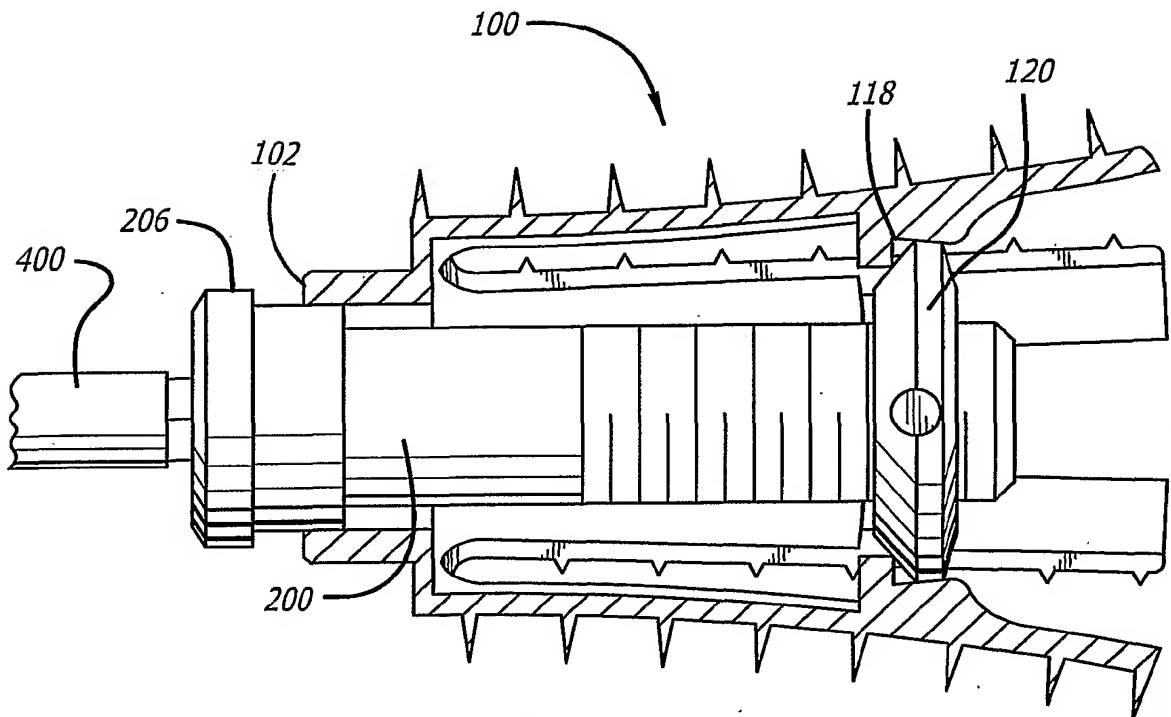


FIG. 28

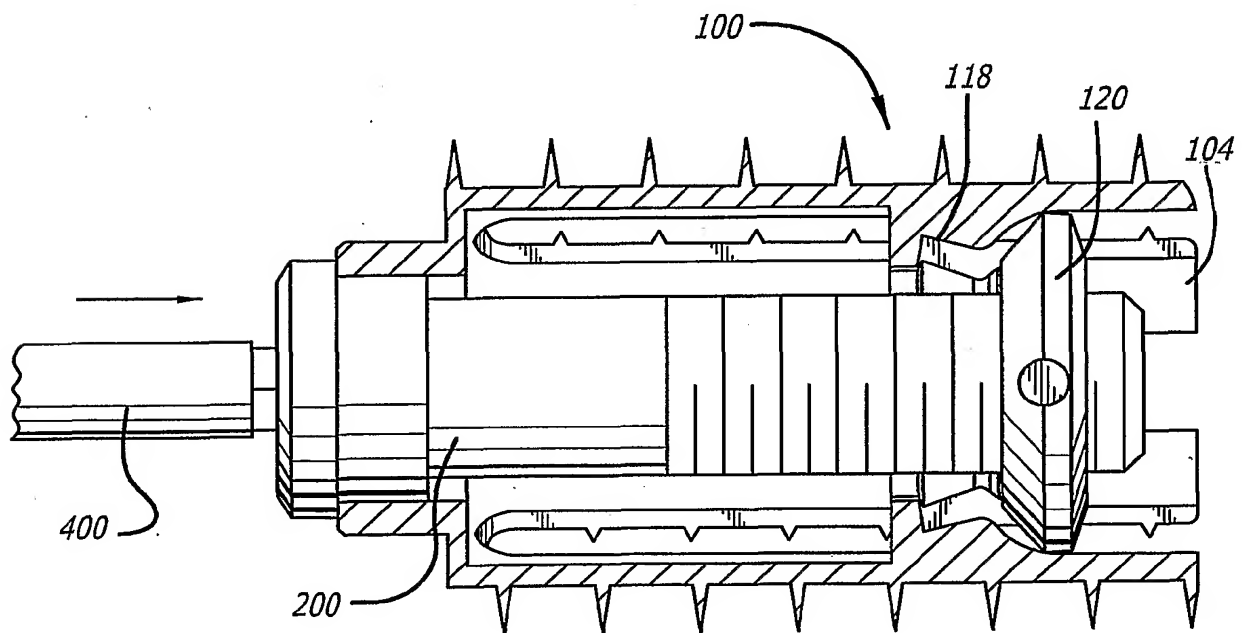
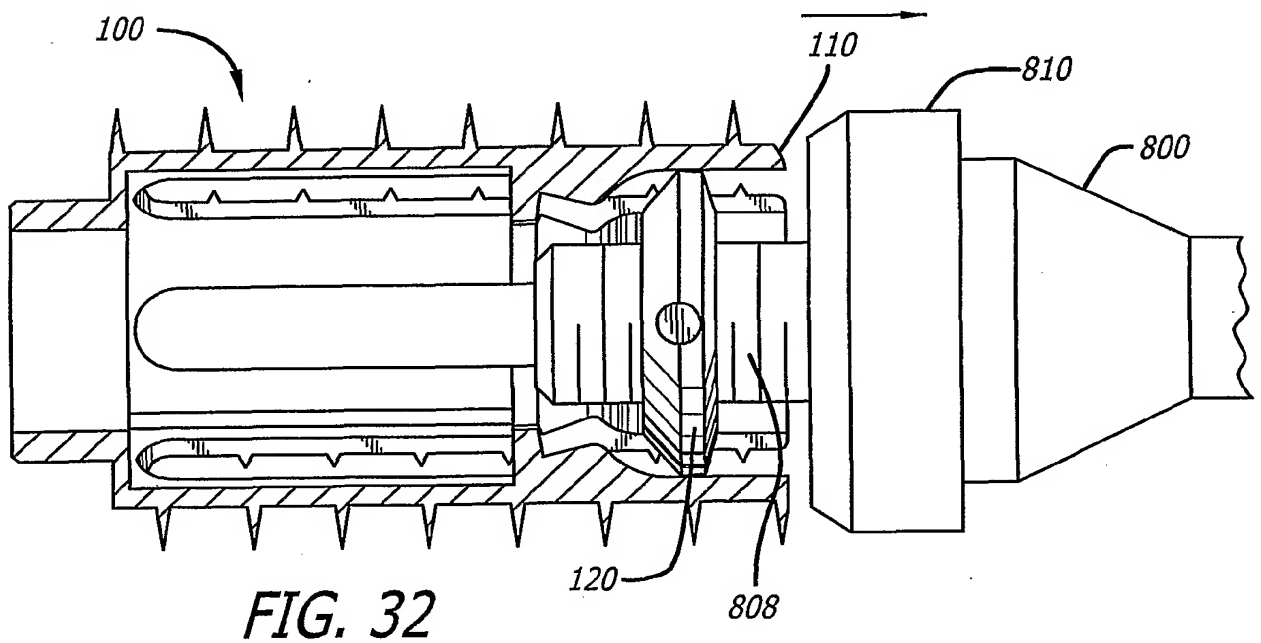
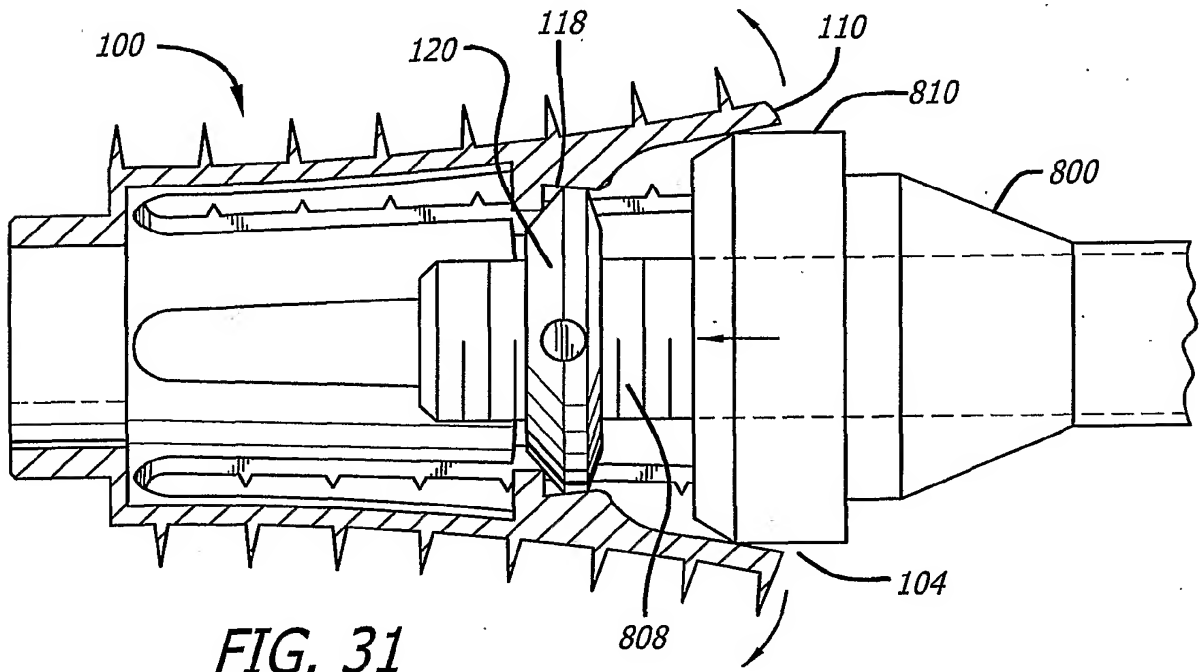
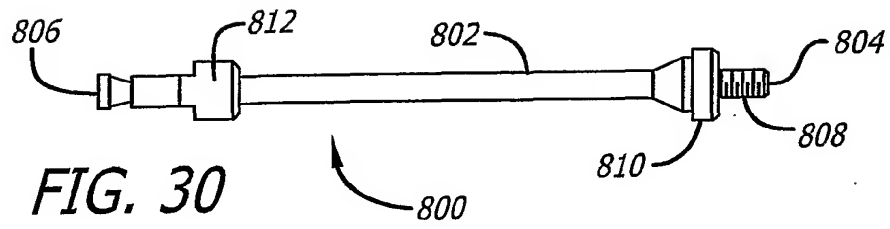


FIG. 29

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FIG. 33

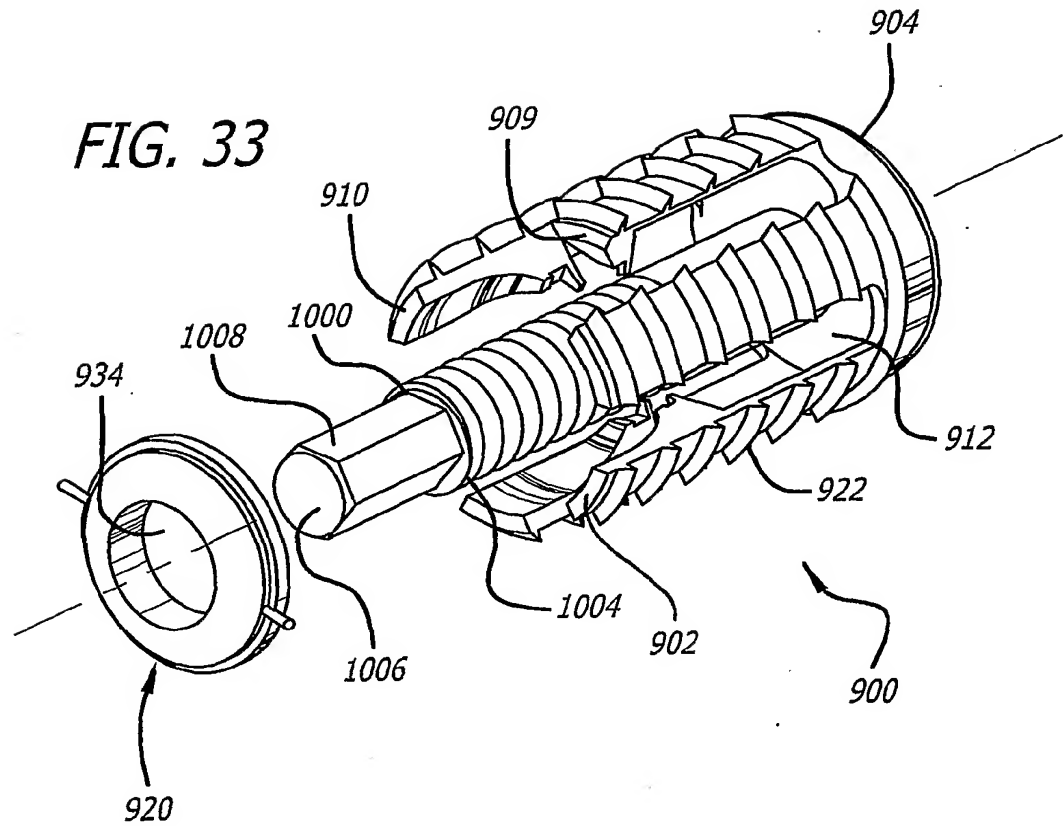


FIG. 39

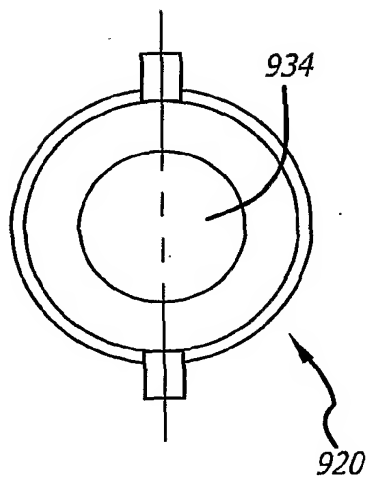


FIG. 40

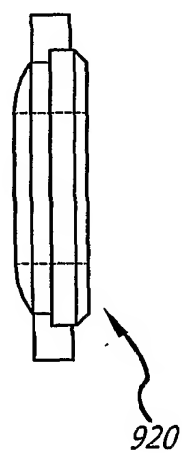
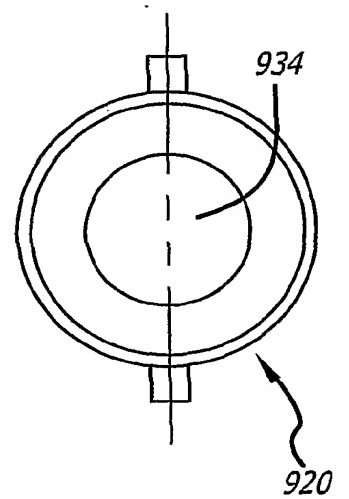


FIG. 41



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FIG. 36

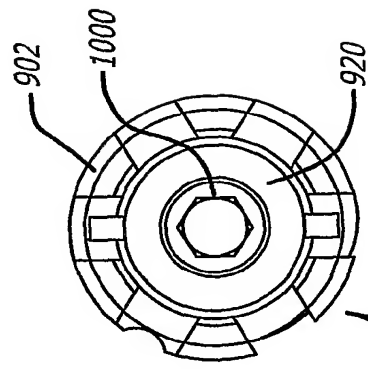


FIG. 34

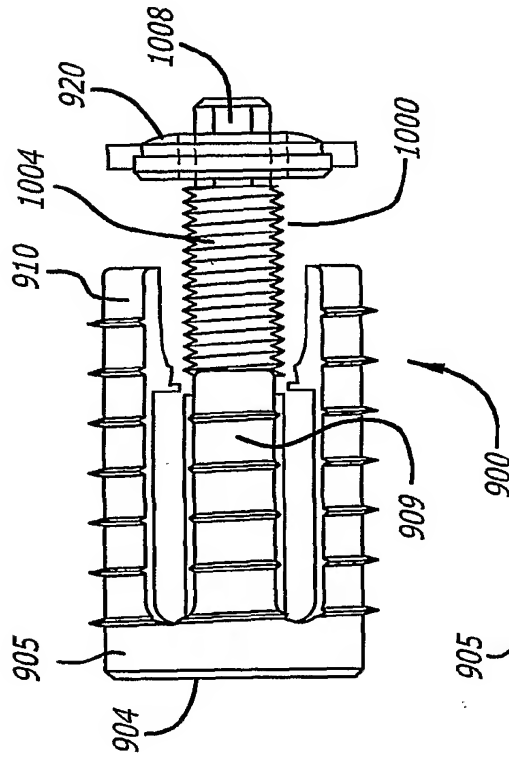


FIG. 35

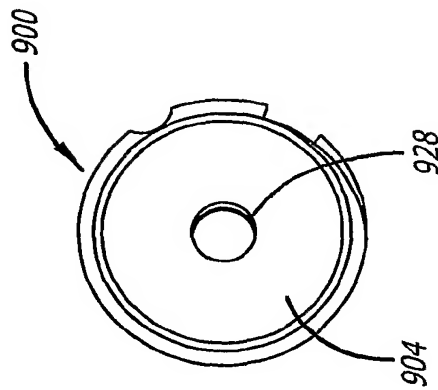


FIG. 37

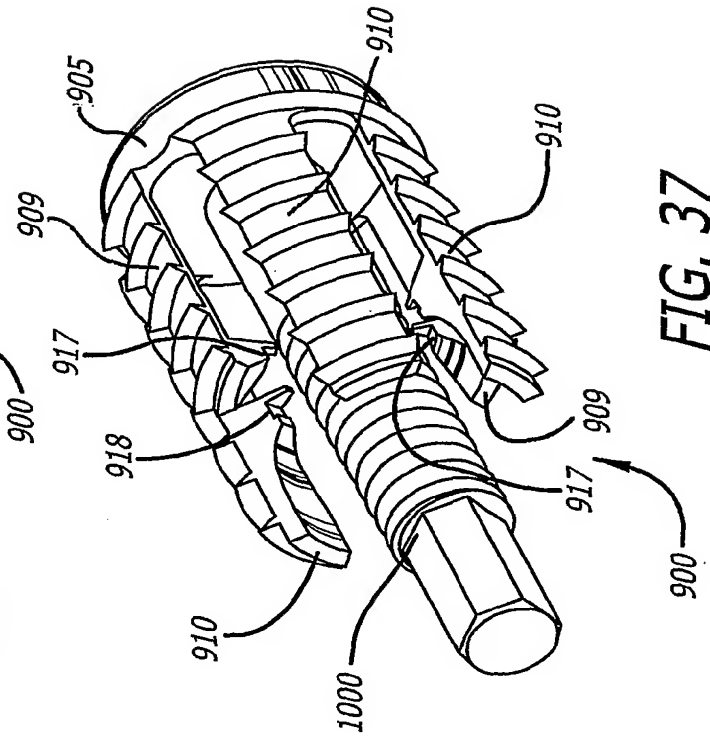
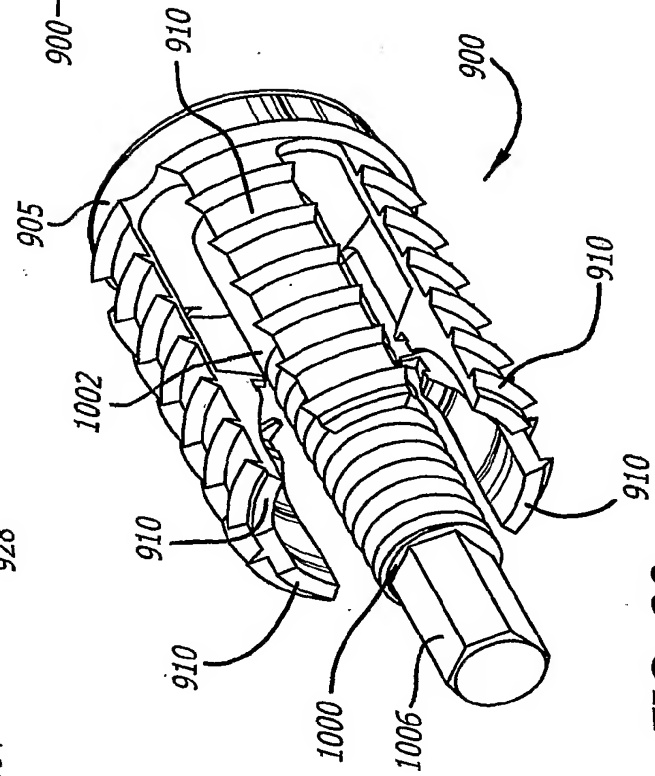
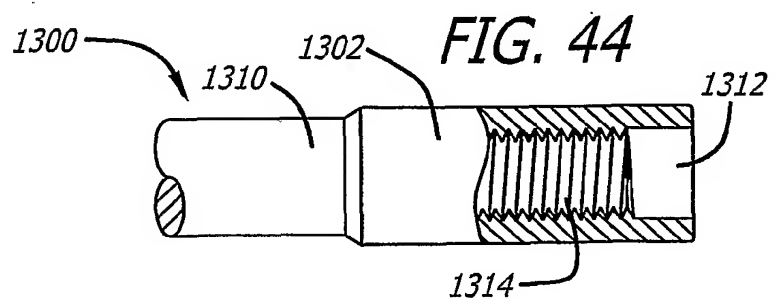
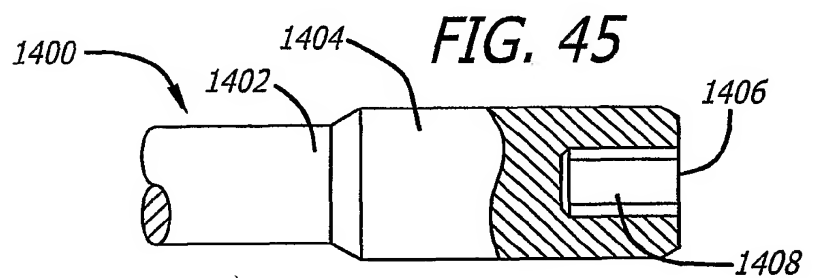
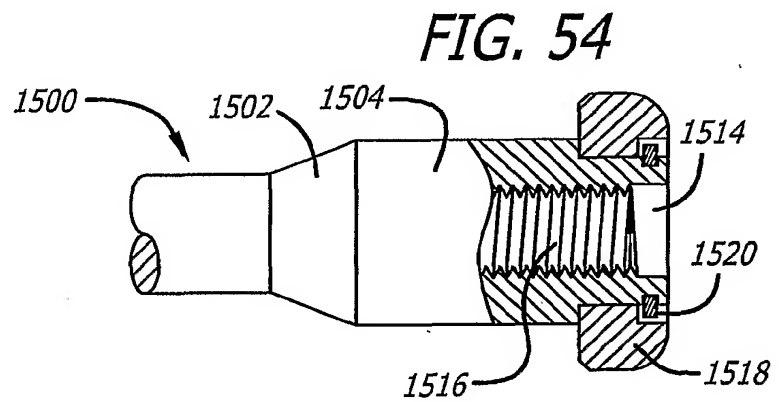
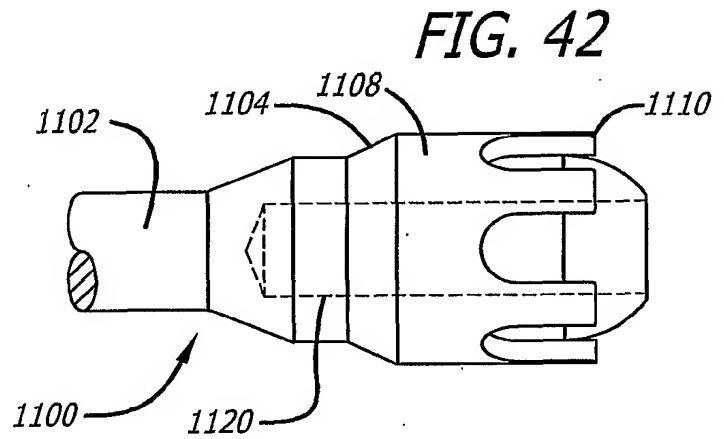
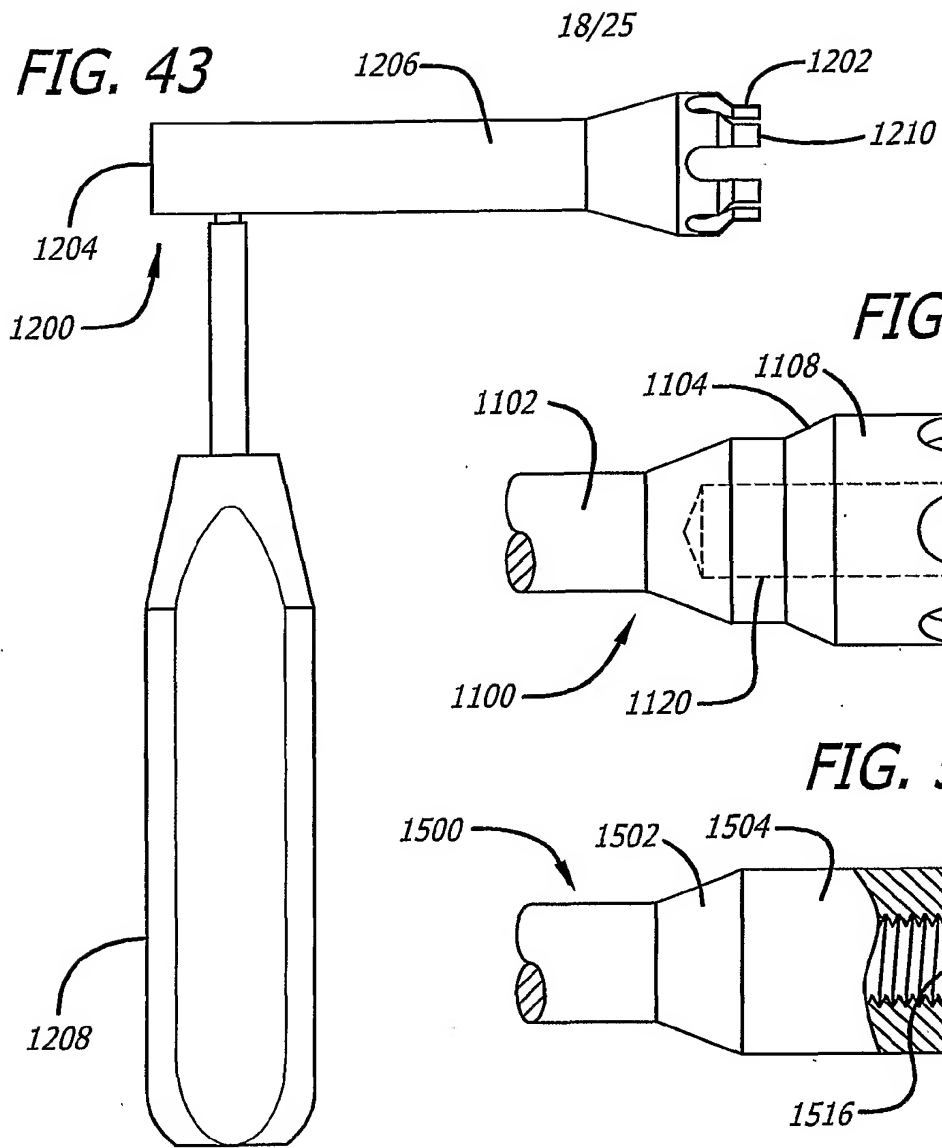


FIG. 38







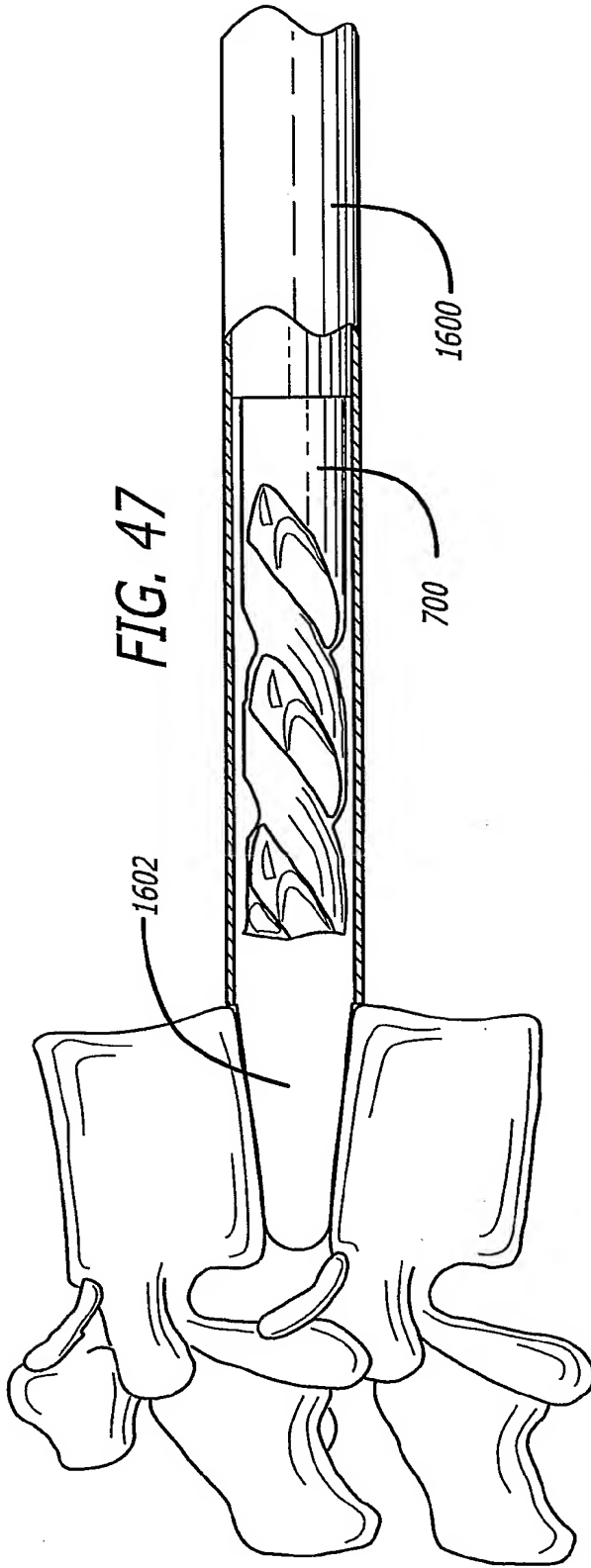
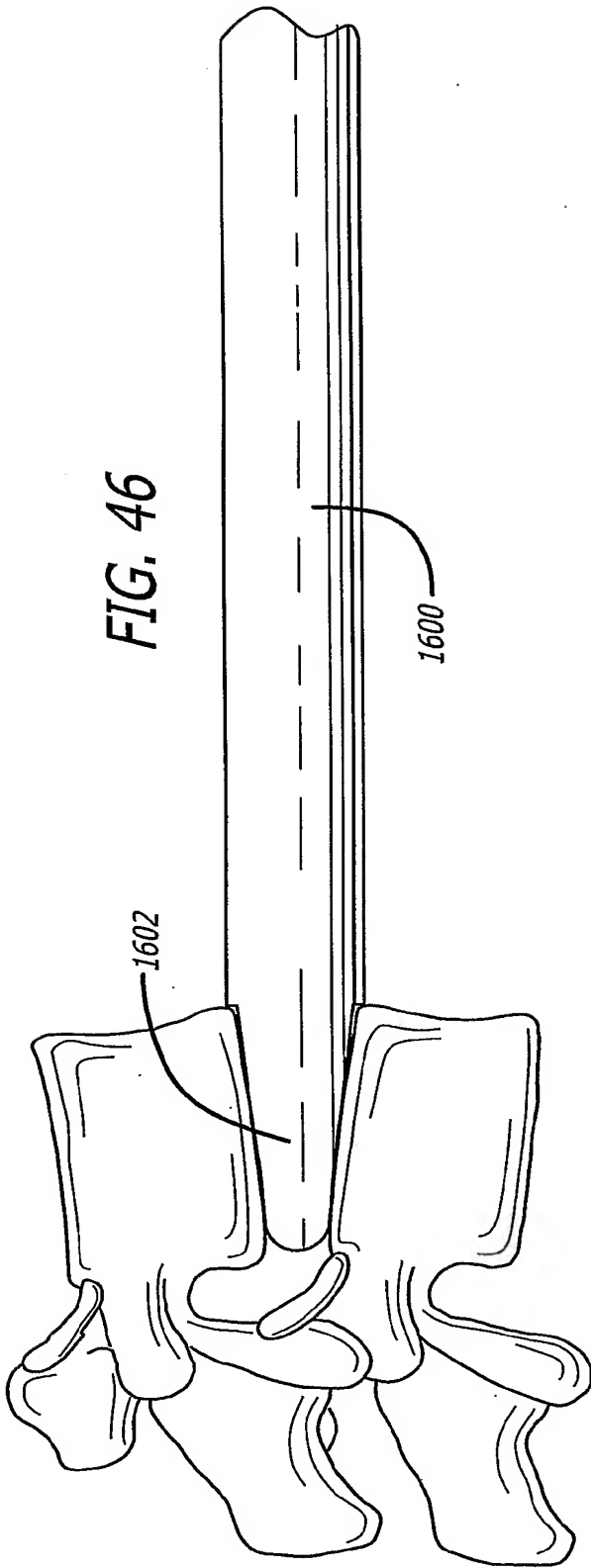
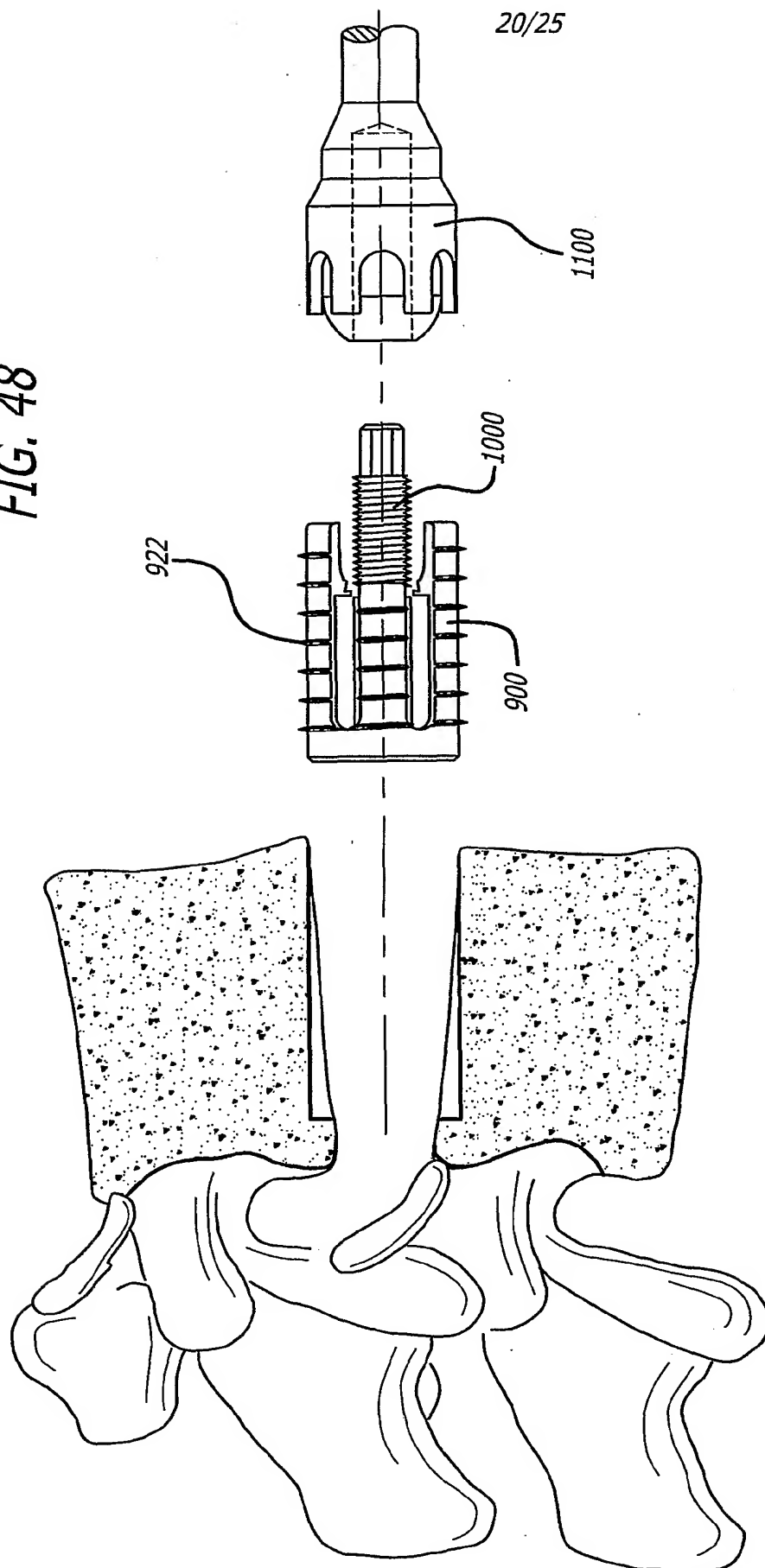
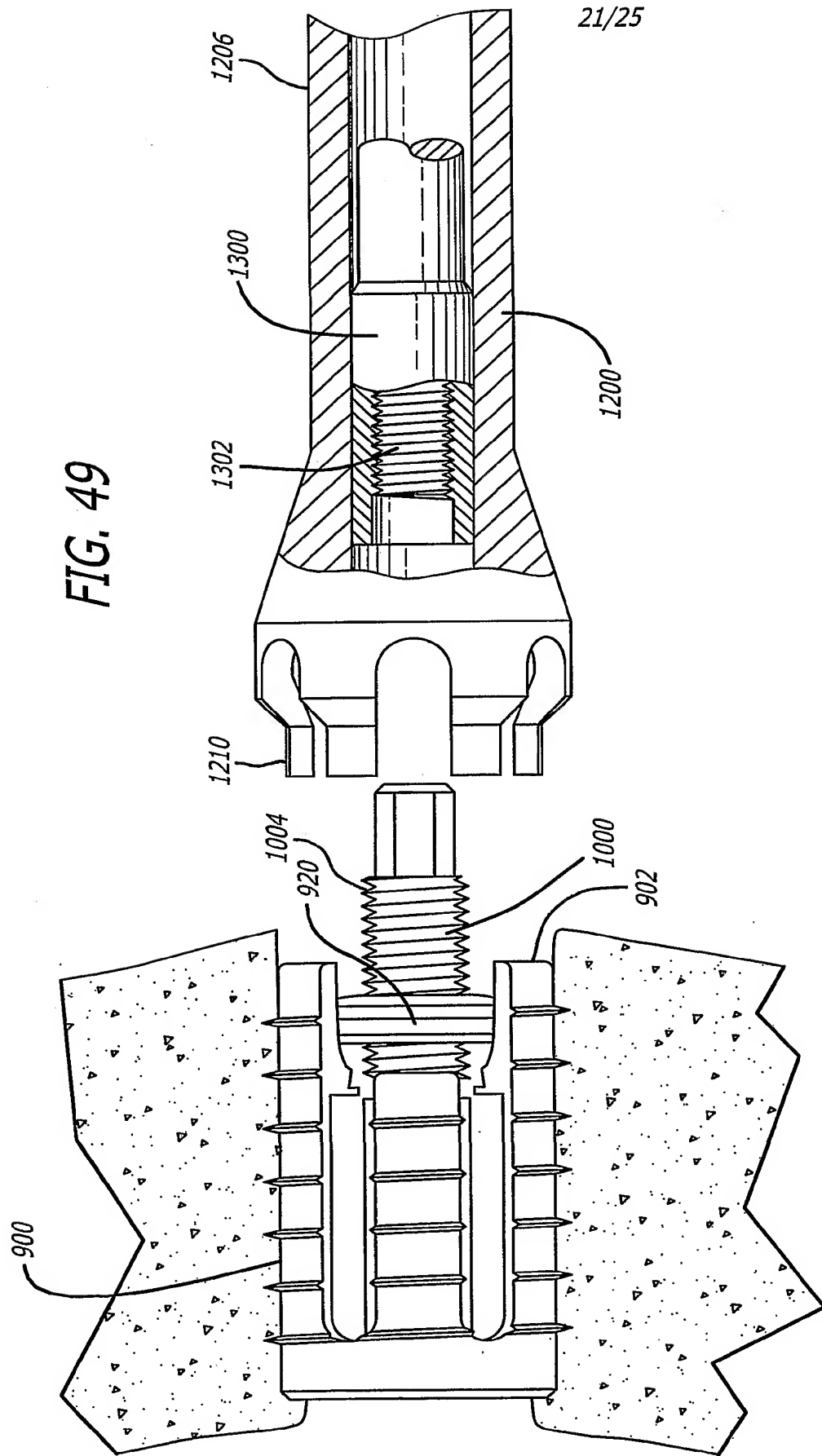
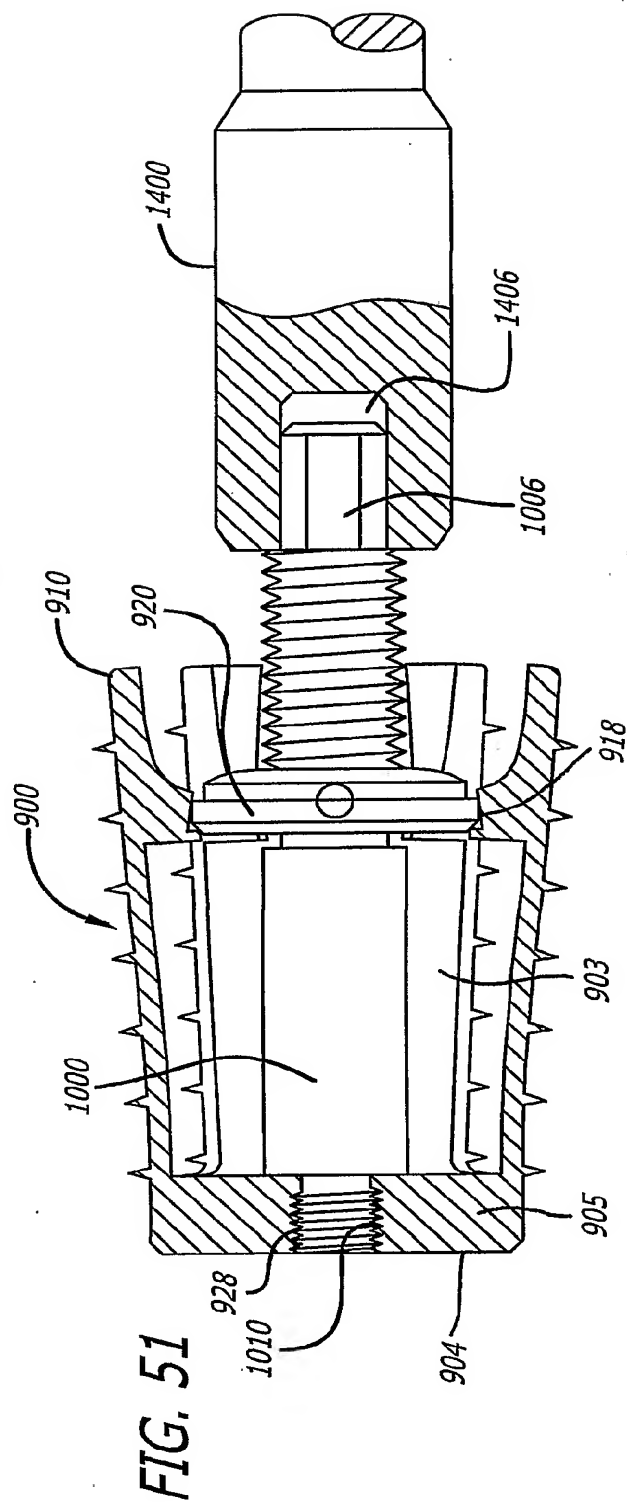
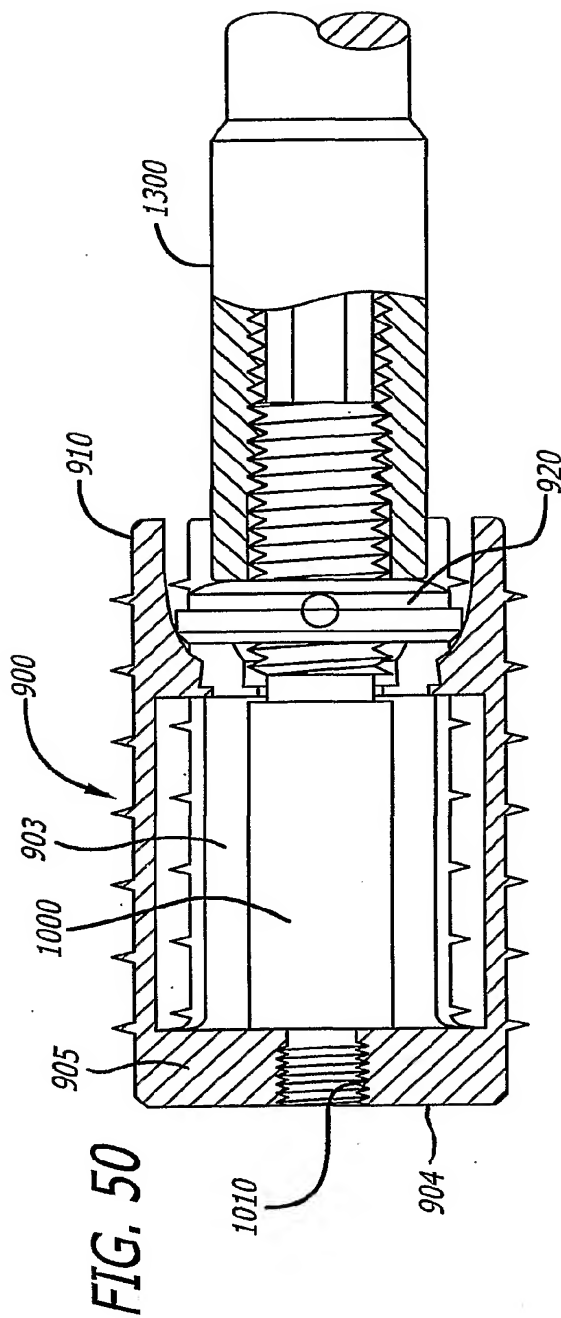


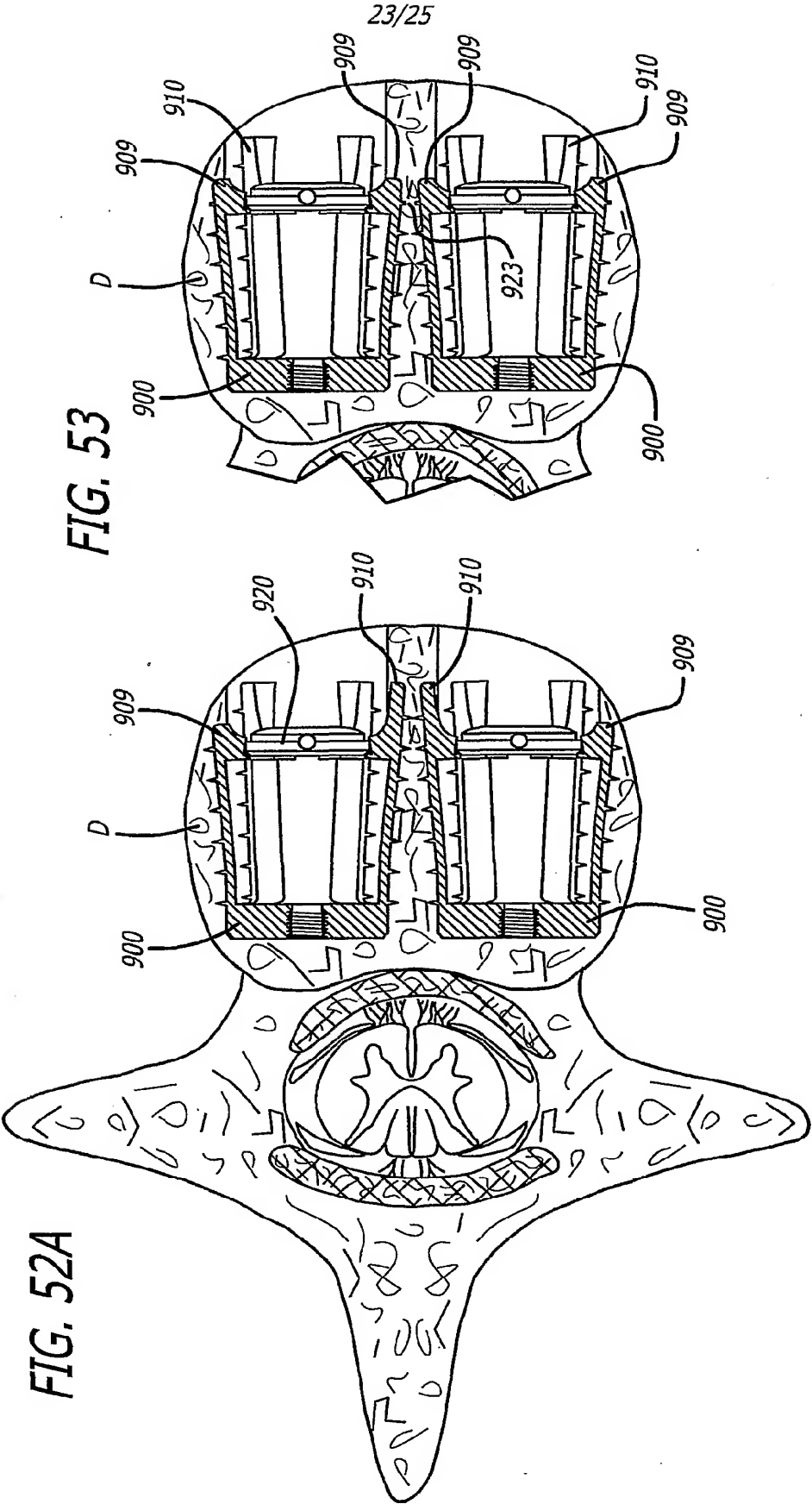
FIG. 48



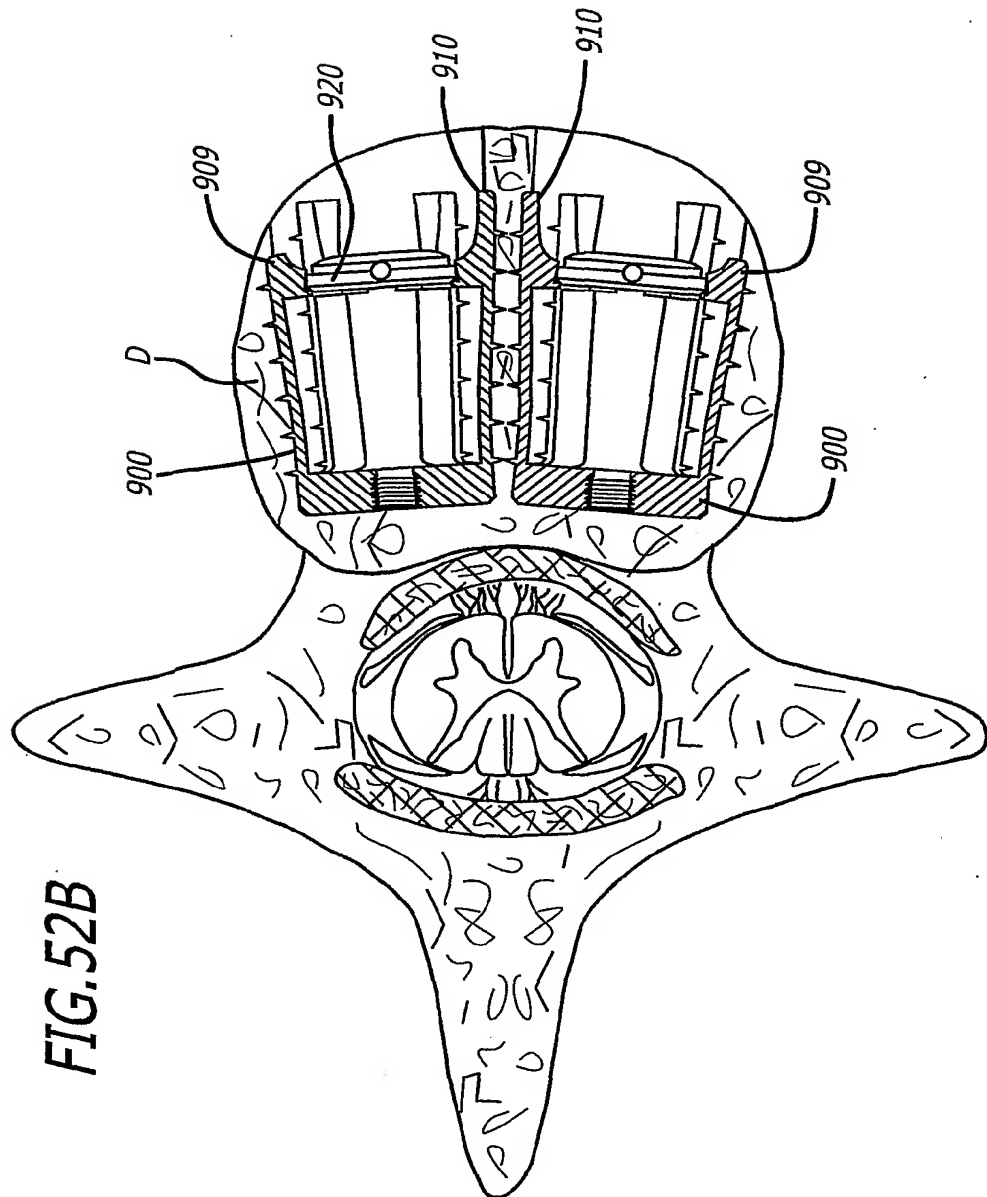


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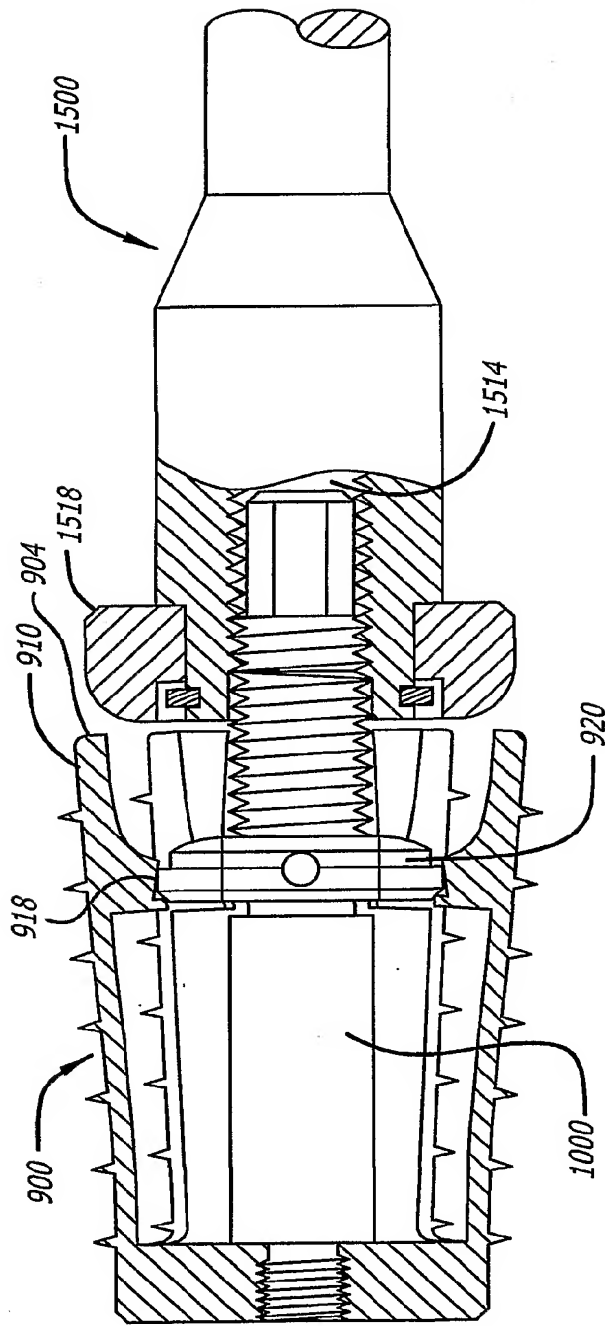


FIG. 55

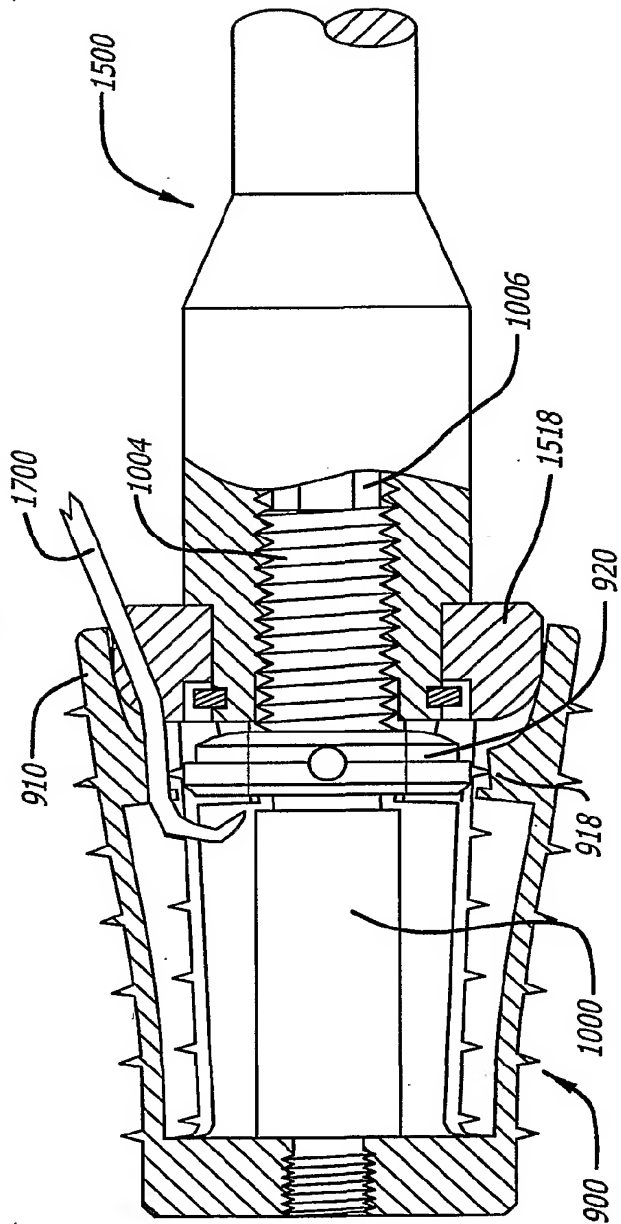


FIG. 56

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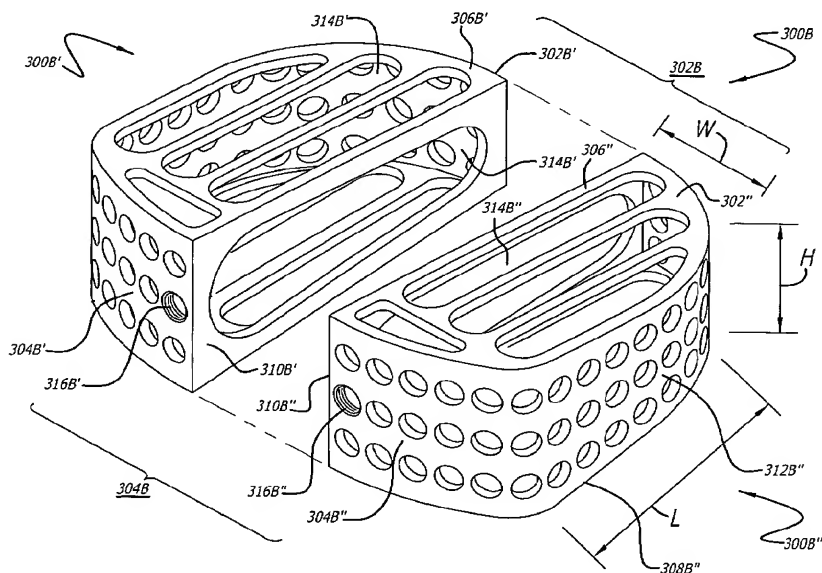
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(54) Title: CONTOURED SPINAL FUSION IMPLANTS



(57) Abstract: An interbody spinal implant adapted for placement across an intervertebral space formed across the height of a disc between two adjacent vertebral bodies. The implant has a leading end that includes at least a portion of an arc of a circle from side to side, and sides that are at least in part straight or a trailing end having a radius of curvature of another circle from side to side. The implant may be made cortical bone, a bone composite, or a material other than bone.



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## CONTOURED SPINAL FUSION IMPLANTS

### Related applications

This application claims priority to provisional application no. 60/281,187, filed April 3, 2001, and provisional application no. 60/281,112, filed April 2, 2001, both of which are incorporated by reference herein.

### Field of the Invention

The present invention relates generally to interbody spinal implants preferably adapted for placement into an implantation space created across the height of a disc space between two adjacent vertebral bodies for the purpose of correcting spinal disease at that interspace. The implants are adapted such that fusion occurs at least in part through the implants. The implant may be made cortical bone, a bone composite, or a material other than bone.

### Description of the Related Art

Implants for placement between adjacent vertebral bodies in the spine come in a variety of shapes and sizes and are made of a variety of materials. Such implants for use in human spinal surgery include implants made of bone or selected inert materials, such as titanium, that have a structure designed to promote fusion of the adjacent vertebral bodies by allowing bone to grow through the implant to thereby fuse the adjacent vertebral bodies.

Implants made of bone and utilized in interbody spinal surgery are often formed from a portion of the diaphysis. The diaphysis is the shaft of a major long bone between the epiphyses, the ends of the bone forming the joints.

A diaphyseal ring is formed by making two spaced apart cuts approximately perpendicular to the long axis of the diaphyseal portion of a major long bone with the medullary canal forming an opening through the ring. Such rings are generally harvested from femurs for use in the lumbar spine. Other bones from the arm or leg or other part of the human skeleton may be useful in various regions of the spine.

The cuts are generally spaced apart so as to form a ring of bone having a height corresponding to the restored disc space or slightly greater. Diaphyseal ring bone grafts are placed into the spine within and across the height of the space previously occupied by a spinal disc between adjacent vertebral bodies to

achieve interbody fusion of those vertebral bodies through the disc space. The diaphyseal ring bone graft is incorporated into the bony fusion over time.

Interbody spinal fusion with diaphyseal bone rings, however, has had limited success in the past. While all the causes for failure may not yet be appreciated, it is nevertheless believed that a failure to gain congruity at the interfaces of the bone ring implant to the adjacent vertebral bodies, and a failure to achieve stability of the bone ring implant, may be two of the more significant factors subject to the surgeon's control contributing to such failures.

At the time of surgery, where fusion is intended to occur between adjacent vertebral bodies of a patient's spine; the surgeon typically prepares an opening at the site of the intended fusion by removing some or all of the disc material that exists between the adjacent vertebral bodies to be fused. Because the outermost layers of bone of the vertebral end plate are relatively inert to new bone growth, the surgeon must work on the end plate to remove at least the outermost cell layers of bone to gain access to the blood-rich, vascular bone tissue within the vertebral body. In this manner, the vertebrae are prepared in a way that encourages new bone to grow into or through an implant that is placed between the vertebral bodies.

Present methods of forming this space between adjacent vertebral bodies generally include the use of one or more of the following: hand held biting and grasping instruments known as rongeurs; drills and drill guides; rotating burrs driven by a motor; osteotomes and chisels, and a double wheel cutter or vertebral interspace preparation device. In particular, the double wheel cutter or vertebral interspace preparation device, as disclosed by Michelson in WO 99/63891, incorporated herein by reference, is adapted for linear insertion, i.e., insertion along a single axis, and without the need to substantially move the device from side to side within the disc space along a second axis. In such a preferred embodiment, the device has at its working end an abrading element having a width generally corresponding to the width of the implant to be implanted.

There is a desire to improve congruity at the interfaces of the implant to the adjacent vertebral bodies, and to achieve stability of the implant. Therefore it is advantageous for the contour of the implants to closely match the implantation space formed between and at least in part into the adjacent vertebral bodies to

allow a more uniform load transfer across the implant between the vertebral bodies.

Interbody spinal implants that are entirely or almost entirely made of cortical bone or a bone composite material offer the advantages of that material including an appropriate modulus of elasticity and strength for the prescribed use, the capacity to be bioactive, including being osteoconductive, osteoinductive, osteogenic, and to more generally provide a good substrate for the formation of new bone as fusion occurs. Further, by being bioabsorbable the bone material is replaced by the patient's own bone over time, thereby preventing stress shielding and leading to the eventual elimination of any foreign body from the implantation site. As it is desirable to take advantage of all these benefits, there exists a need for an improved interbody spinal fusion implant made of bone, a bone composite material, or a material other than bone having a configuration that provides for an improved congruity of the implant to the vertebral bodies and improved implant stability.

#### SUMMARY OF THE INVENTION

In accordance with the purposes of the present invention, as embodied and broadly described herein, an interbody spinal fusion implant made of cortical bone is provided for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine. The implant includes a leading end for insertion first into the disc space and a trailing end opposite the leading end. The implant has a length from the leading end to the trailing end. The leading end is configured in the shape of half a circle from side to side. The implant also includes opposed upper and lower portions between the leading and trailing ends that are adapted to be placed within the disc space to contact and support the adjacent vertebral bodies. The upper and lower portions are non-arcuate along at least a portion of the length of the implant. The implant also includes opposite sides between the upper portion and lower portion, and between the leading and trailing ends. At least one of the opposite sides is at least in part straight along at least a portion of the length of the implant.

In accordance with the purposes of the present invention, as embodied and broadly described herein, an interbody spinal fusion implant made of cortical bone is provided for insertion at least in part into an implantation space formed

across the height of a disc space between adjacent vertebral bodies of a human spine. The implant includes a leading end for insertion first into the disc space and a trailing end opposite the leading end. The implant has a length from the leading end to the trailing end. The leading end is configured from side to side in the shape of approximately one half of a first circle. The trailing end has a radius of curvature of a second circle from side to side. The second circle has a radius greater than the radius of the first circle. The implant also includes opposed upper and lower portions between the leading and trailing ends that are adapted to be placed within the disc space to contact and support the adjacent vertebral bodies. The implant has a maximum width that is greater than one-half of the width of the adjacent vertebral bodies into which the implant is adapted to be inserted.

The implants mentioned above are preferably manufactured from a bone ring obtained from a major long bone of a human having a medullary canal. The implant includes at least a portion of the medullary canal passing through the upper and lower portions to form a passage adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through the passage. Alternatively, the implants mentioned above may be manufactured from a bone composite material.

In accordance with the purposes of the present invention, as embodied and broadly described herein, an artificial interbody spinal fusion implant made of a material other than bone is provided for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine. The implant includes a leading end for insertion first into the disc space and a trailing end opposite the leading end. The implant has a length from the leading end to the trailing end. The leading end is configured in the shape of approximately one half of a circle from side to side. The implant also includes opposed upper and lower portions between the leading and trailing ends that are adapted to be placed within the disc space to contact and support the adjacent vertebral bodies. The upper and lower portions are non-arcuate along at least a portion of the length of the implant. The upper and lower portions include at least one opening in communication with one another and adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through the implant. The implant

also includes opposite sides between the upper portion and lower portion, and between the leading and trailing ends. At least one of the opposite sides is at least in part straight along at least a portion of the length of the implant.

In accordance with the purposes of the present invention, as embodied and broadly described herein, an artificial interbody spinal fusion implant made of a material other than bone is provided for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine. The implant includes a leading end for insertion first into the disc space and a trailing end opposite the leading end. The implant has a length from the leading end to the trailing end. The leading end is configured from side to side in the shape of approximately one half of a first circle. The trailing end has a radius of curvature of a second circle from side to side. The second circle has a radius greater than the radius of the first circle. The implant also includes opposed upper and lower portions between the leading and trailing ends that are adapted to be placed within the disc space to contact and support the adjacent vertebral bodies. The upper and lower portions include at least one opening in communication with one another and adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through the implant. The implant has a maximum width that is greater than one-half of the width of the adjacent vertebral bodies into which the implant is adapted to be inserted.

Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top plan view of a vertebral body in the lumbar spine with an implantation space formed to receive a spinal implant having a radius of curvature at the leading end that is less than the radius of curvature of the trailing end of the anterior aspect of the vertebral body between the sides of the implantation space.

Fig. 2 is a side elevation view of two adjacent vertebral bodies in the lumbar spine with the implantation space of Fig. 1 formed across the height of the spinal disc and into the adjacent vertebral bodies.

Fig. 3 is a side perspective view of the implantation space of Fig. 1.

Fig. 4 is a top plan view of a vertebral body in the cervical spine with an implantation space formed to receive a spinal implant having a radius of curvature at the leading end that is less than the radius of curvature of the trailing end of the anterior aspect of the vertebral body.

Fig. 5 is a side elevation view of two adjacent vertebral bodies in the cervical spine with the implantation space of Fig. 4 formed across the height of the spinal disc and into the adjacent vertebral bodies.

Fig. 6 is a side perspective view of the implantation space of Fig. 4.

Fig. 7 is a top plan view of a vertebral body in the lumbar spine and a preferred embodiment of an implant in accordance with the present invention installed into the implantation space of Fig. 1.

Fig. 8 is a side elevation view of two adjacent vertebral bodies with the implant of Fig. 7 installed into the implantation space of Fig. 1 formed across the height of the spinal disc and into the adjacent vertebral bodies.

Fig. 9 is a top plan view of the implant of Fig. 7.

Fig. 10 is a side elevation view of the implant of Fig. 7.

Fig. 11 is a leading end view of the implant of Fig. 7.

Fig. 12 is a trailing end view of the implant of Fig. 7.

Fig. 13 is a top plan view of a vertebral body in the lumbar spine and another preferred embodiment of an implant in accordance with the present invention installed into the implantation space of Fig. 1.

Fig. 14 is a side elevation view of two adjacent vertebral bodies with the implant of Fig. 13 installed into the implantation space of Fig. 1 formed across the height of the spinal disc and into the adjacent vertebral bodies.

Fig. 15 is a top plan view of the implant of Fig. 13.

Fig. 16 is a side elevation view of the implant of Fig. 13.

Fig. 17 is a leading end view of the implant of Fig. 13.

Fig. 18 is a trailing end view of the implant of Fig. 13.

Fig. 19 is a top plan view of another preferred embodiment of an implant in accordance with the present invention for use in the implantation space of Fig. 4.

Fig. 20 is a top plan view of another preferred embodiment of an implant in accordance with the present invention for use in the implantation space of Fig. 4.

Fig. 21 is a rear perspective view of another preferred embodiment of an implant in accordance with another preferred embodiment of the present invention having two members that are preferably mirror images of one another.

Fig. 22 is a top plan view of one of the members of the implant of Fig. 21.

Fig. 23 is an interior side elevation view of one of the members of the implant of Fig. 21.

Fig. 24 is an exterior side elevation view of one of the members of the implant of Fig. 21.

Fig. 25 is a leading end view of one of the members of the implant of Fig. 21.

Fig. 26 is a trailing end view of one of the members of the implant of Fig. 21.

Fig. 27 is a rear perspective view of another preferred embodiment of an implant in accordance with another preferred embodiment of the present invention having two members that are preferably mirror images of one another.

Fig. 28 is a top plan view of one of the members of the implant of Fig. 27.

Fig. 29 is an interior side elevation view of one of the members of the implant of Fig. 27.

Fig. 30 is an exterior side elevation view of one of the members of the implant of Fig. 27.

Fig. 31 is a leading end view of one of the members of the implant of Fig. 27.

Fig. 32 is a trailing end view of one of the members of the implant of Fig. 27.

Fig. 33 is a top plan view of another preferred embodiment of an implant in accordance with the present invention and a second implant that is a mirror image thereof illustrated in dashed line, both implants being shown implanted from an anterior approach to the spine in a vertebral body illustrated in dashed line.

Fig. 34 is a top plan view of another preferred embodiment of an implant in accordance with the present invention and a second implant that is a mirror image thereof illustrated in dashed line, both implants being shown implanted

from an anterior approach to the spine in a vertebral body illustrated in dashed line.

Fig. 35 is a top plan view of another preferred embodiment of an implant in accordance with the present invention and a second implant that is a mirror image thereof illustrated in dashed line, both implants being shown implanted from a posterior approach to the spine in a vertebral body illustrated in dashed line.

Fig. 36 is a top plan view of another preferred embodiment of an implant in accordance with the present invention with bone engaging screws.

Fig. 37 is a side elevation view of the implant of Fig. 36.

Fig. 38 is a leading end view of the implant of Fig. 36.

Fig. 39 is a trailing end view of the implant of Fig. 36 with the bone engaging screws and lock installed.

Fig. 40 is a trailing end view of the implant of Fig. 39 without the bone engaging screws and lock installed.

Fig. 41 is a partial cross sectional side view of a preferred embodiment of a bone screw lock in accordance with the present invention for use with the implant of Fig. 36.

Fig. 42 is a cross sectional side view of another preferred embodiment of a bone screw lock in accordance with the present invention.

Fig. 43 is a top plan view of another preferred embodiment of an implant in accordance with the present invention with bone engaging screws.

Fig. 44 is a side elevation view of the implant of Fig. 43.

Fig. 45 is a leading end view of the implant of Fig. 43.

Fig. 46 is a trailing end view of the implant of Fig. 43 with the bone engaging screws and lock installed.

Fig. 47 is a trailing end view of the implant of Fig. 46 without the bone engaging screws and lock installed.

Fig. 48 is a partial cross sectional side view of a preferred embodiment of a bone screw lock in accordance with the present invention for use with the implant of Fig. 43.

Fig. 49 is a cross sectional side view of another preferred embodiment of a bone screw lock in accordance with the present invention.



### DETAILED DESCRIPTION OF THE INVENTION

The following description is intended to be representative only and not limiting and many variations can be anticipated according to these teachings, which are included within the scope of this inventive teaching. Reference will now be made in detail to the preferred embodiments of this invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

Figs. 1-3 show an implantation space 50 formed across the height of the space occupied by a spinal disc D and into vertebral bodies V in the lumbar spine. Implantation space 50 is preferably formed with the apparatus and method disclosed by Michelson in U.S. Patent No. 6,083,228, and WO 99/63891, the disclosures of which are both incorporated herein by reference. The instruments and method are not the subject matter of this application. It is understood that the preparation of the implantation space shown therein are a preferred instrument and method of preparing the implantation spaces and that any method and instrumentation suitable for the purpose may be utilized to prepare the desired implantation space.

Implantation space 50 is preferably formed in the endplate region ER in the subchondral bone of the vertebral body V. Implantation space 50 preferably is formed to have a leading edge 52 with a shape from side to side of approximately one-half of a first circle A. The trailing portion 54 of implantation space 50 preferably includes at least a portion of the anterior aspect of the vertebral body having a radius of curvature of a second circle B from side to side. Preferably the radius of circle A is less than the radius of circle B. Implantation space 50 may further include side edges 56, 58. Side edges 56, 58 preferably include at least a straight portion, may be parallel to one another along lines P and form a curved transition with leading edge 52.

Figs. 4-6 show an implantation space 60 formed across the height of the space occupied by a spinal disc D and into vertebral bodies V in the cervical spine. Implantation space 60 preferably is formed to have a leading edge 62 with a shape from side to side of approximately one half of a first circle A. The trailing portion of implantation space 60 preferably includes at least a portion of the anterior aspect of the vertebral body having a radius of curvature of a second

circle C from side to side. Preferably the radius of circle A is less than the radius of circle C. Implantation space 60, however, preferably does not have straight side edges like implantation space 50 because the anterior to posterior depth of cervical vertebral bodies is less than the anterior to posterior depth of lumbar vertebral bodies. Thus, the radius of circle C is smaller in the cervical spine than the radius of circle B in the lumbar spine.

Figs. 7-12 show an implant 100A in accordance with a preferred embodiment of the present invention. Implant 100A is preferably manufactured from a bone ring obtained from a major long bone of a human. Implant 100A has a leading end 102A for insertion first into the disc space between two adjacent vertebral bodies and a trailing end 104A opposite leading end 102A, and opposite sides 110A, 112A therebetween. Leading end 102A is preferably configured to match the contour of leading edge 52 of implantation space 50 and trailing end 104A is preferably configured to conform to the contour of the anterior aspect of the vertebral body at trailing portion 54 of implantation space 50. Sides 110A, 112A are generally planar and preferably correspond to the configuration of side edges 56, 58 of implantation space 50.

In a preferred embodiment of the present invention, leading end 102A, trailing end 104A, and opposite sides 110A, 112A are machined to have various configurations. Leading end 102A is preferably machined to have a shape of approximately half a first circle from side to side. Where the implantation space is prepared into the vertebral bodies to have a lip or ridge that is at least in part curved, leading end 102A may be adapted to abut at least that portion of the implantation space.

One or both of sides 110A, 112A may also be formed to be at least in part oriented generally parallel to the mid-longitudinal axis of implant 100A and/or to each other. Further, leading end 102A may be tapered to facilitate insertion of implant 100A between the two adjacent vertebral bodies.

Trailing end 104A preferably forms an arc of a second circle from side to side having a radius greater than the radius of the first circle associated with leading end 102A. Preferably, at least a portion of trailing end 104A is adapted to conform to at least a portion of the peripheral contour of the anterior aspect of the vertebral bodies adjacent the disc space into which the implant is adapted to be inserted, though the invention is not so limited.

Fig. 12 shows that implant 100A preferably has a driver opening 116A at trailing end 104A for cooperatively engaging an instrument for installing implant 100A into the implantation space. Driver opening 116A is preferably configured for threaded engagement with an insertion instrument.

Figs. 8, 10, and 11 show at least a portion of upper and lower surfaces 106A, 108A in an angular relationship to each other from trailing end 104A to leading end 102A for allowing for angulation of the adjacent vertebral bodies relative to each other. Preferably, upper and lower surfaces 106A, 108A are non-arcuate in a direction along the mid-longitudinal axis of implant 100A. Implant 100A preferably has a maximum height that is less than the maximum width of the implant.

As shown in Fig. 9, upper and lower surfaces 106A, 108A preferably have a passage 114A passing therethrough between leading and trailing ends 102A, 104A, respectively, and opposite sides 110A, 112A. Passage 114A is preferably adapted to hold bone growth promoting material to permit for the growth of bone from vertebral body to vertebral body through passage 114A. In addition to passage 114A, upper and lower surfaces 106A, 108A may include at least one opening in communication with one another to permit for the growth of bone from vertebral body to vertebral body through implant 100A, though the invention is not so limited. Upper and lower surfaces 106A, 108A may also be porous and may include a bone ingrowth surface.

As shown in Fig. 9, the implants described herein may include a bone-engaging surface 118A such as knurling for example. Bone engaging surface 118A is configured to engage the bone of the adjacent vertebral bodies to maintain implant 100A within the adjacent vertebral bodies after implantation. Other preferred embodiments of bone-engaging surfaces may include the surfaces of the implant being roughened, ratcheted, splined, or may include at least one protrusion to penetrably engage the bone of the vertebral bodies. By way of example only, the implants of the present invention may include the surface configuration taught by Michelson in U.S. Patent Application No. 09/457,228, entitled "Spinal Implant Surface Configuration," the disclosure of which is incorporated by reference herein.

Implant 100A is preferably, but need not be manufactured from a diaphyseal bone ring. The diaphyseal bone ring is preferably obtained from a

major long bone of the human skeleton. The bone ring is formed by making two spaced apart cuts approximately perpendicular to the long axis of the diaphyseal portion of the major long bone with a portion of the medullary canal forming an opening through the ring. Such rings are generally harvested from femurs for use in the lumbar spine. Other bones from the arm or leg or other part of the human skeleton may be useful in various regions of the spine. The cuts may be made into the long bone generally perpendicular to or at other angles transverse to the long axis of the diaphyseal bone to form the bone ring having upper and lower surfaces. Making the cuts at an angle to each other creates a bone ring with upper and lower surfaces that are angled relative to each other. The angular relationship of the upper and lower surface of the bone ring, when subsequently formed into an implant and implanted into the spine, position the adjacent vertebral bodies in angular relationship to each other to restore the natural curvature of the spine, such as lordosis for example.

The bone may be machined to form an implant having a selected shape suitable for the intended purpose. Examples of tools which may be used to machine the implant include, but are not limited to, burrs, reamers, mills, saws, trephines, chisels, and the like. For example only, the leading end may be shaped to be approximately half a circle from side to side. The sides may be machined to be at least in part straight. The trailing end may be machined to any desired shape suitable for the intended purpose and may preferably be shaped to conform to the anatomical contour of the adjacent vertebral bodies between which the implant is adapted to be inserted. The medullary canal preferably forms a passage adapted to hold bone growth promoting materials and/or substances. Where it is appropriate, it may be desirable to preserve at least a portion of the natural curvature of the perimeter of the bone ring as part of the configuration of the implant shape.

Implant 100A preferably has a length greater than one-half the depth of the vertebral bodies adjacent the disc space into which the implant is adapted to be inserted as measured between the anterior and posterior aspects of the vertebral bodies. Implant 100A also preferably has a maximum width that is greater than one-half the width of the adjacent vertebral bodies into which the implant is adapted to be inserted.

For any of the embodiments of the implants of the present invention made at least in part of bone, instead of being machined from a single bone portion, the implant can be manufactured from a composite bone material which may include at least one of cortical bone fibers, bone filaments, bone particles, or bone dust, and a binding material which may or may not be bioactive and/or bioresorbable such as a plastic, ceramic, for example. By way of example only and not limitation, bioresorbable materials may include polygalactone. Once formed, the composite implant material may be machined or molded, into the desired shape.

Figs. 13-18 show an implant 100B preferably made of a material other than bone in accordance with a preferred embodiment of the present invention. Implant 100B has a leading end 102B for insertion first into the disc space between two adjacent vertebral bodies and a trailing end 104B opposite leading end 102B, and opposite sides 110B, 112B therebetween. Leading end 102B is preferably configured to match the contour of leading edge 52 of implantation space 50 and trailing end 104B is preferably configured to conform to the contour of the anterior aspect of the vertebral body at trailing portion 54 of implantation space 50. Sides 110B, 112B are generally planar and preferably correspond to the configuration of side edges 56, 58 of implantation space 50.

In a preferred embodiment of the present invention, leading end 102B, trailing end 104B, and opposite sides 110B, 112B may have various configurations. Leading end 102B is preferably in the shape of approximately half a first circle from side to side. Where the implantation space is prepared into the vertebral bodies to have a lip or ridge that is at least in part curved, leading end 102B may be adapted to abut at least that portion of the implantation space.

One or both of sides 110B, 112B may also be formed to be at least in part oriented generally parallel to the mid-longitudinal axis of implant 100B and/or to each other. One or both of sides 110B, 112B may include at least one opening 119B to permit for the growth of bone therethrough and into implant 100B, though the invention is not so limited. Further, leading end 102B may be tapered to facilitate insertion of implant 100B between the two adjacent vertebral bodies.

Trailing end 104B preferably forms an arc of a second circle from side to side having a radius greater than the radius of the first circle associated with leading end 102B. Preferably, at least a portion of trailing end 104B is adapted to conform to at least a portion of the peripheral contour of the anterior aspect of the

vertebral bodies adjacent the disc space into which the implant is adapted to be inserted, though the invention is not so limited.

Fig. 18 shows that implant 100B preferably has a driver opening 116B at trailing end 104B for cooperatively engaging an instrument for installing implant 100 into the implantation space. Driver opening 116B is preferably configured for threaded engagement with an insertion instrument.

Figs. 14, 16, and 17 show at least a portion of upper and lower surfaces 106B, 108B in an angular relationship to each other from trailing end 104B to leading end 102B for allowing for angulation of the adjacent vertebral bodies relative to each other. Preferably, upper and lower surfaces 106B, 108B are non-arcuate in a direction along the mid-longitudinal axis of implant 100B. Implant 100B preferably has a maximum height that is less than the maximum width of the implant.

As shown in Fig. 15, upper and lower surfaces 106B, 108B preferably have at least one opening 114B passing therethrough between leading and trailing ends 102B, 104B, respectively, and opposite sides 110B, 112B. Openings 114 are preferably adapted to hold bone growth promoting material to permit for the growth of bone from vertebral body to vertebral body through openings 114B and through implant 100B. Upper and lower surfaces 106B, 108B may also be porous and may include a bone ingrowth surface.

As shown in Fig. 15, the implants described herein may include a bone-engaging surface 118B such as knurling for example. Bone engaging surface 118B is configured to engage the bone of the adjacent vertebral bodies to maintain implant 100B within the adjacent vertebral bodies after implantation. Other preferred embodiments of bone-engaging surfaces may include the surfaces of the implant being roughened, ratcheted, splined, or may include at least one protrusion to penetrably engage the bone of the vertebral bodies.

The base material used to form the implant of Figs. 13-18 is preferably a material other than bone. In a preferred embodiment, the material of the implant may be formed of an artificial material such as metal including, but not limited to, titanium and its alloys, ASTM material, cobalt chrome, or tantalum, ceramic, various surgical grade plastics, plastic composites, carbon fiber composites, coral, and can include artificial materials which are at least in part bioresorbable.

Implant 100B preferably has a length greater than one-half the depth of the vertebral bodies adjacent the disc space into which the implant is adapted to be inserted as measured between the anterior and posterior aspects of the vertebral bodies. Implant 100B also preferably has a maximum width that is greater than one-half the width of the adjacent vertebral bodies into which the implant is adapted to be inserted.

Fig. 19 shows another preferred embodiment of the present invention of an implant made of bone or a bone composite for use in the cervical spine generally referred to by the numeral 200A. Implant 200A is preferably configured to conform to the shape of implantation space 60 formed in the endplates of adjacent cervical vertebral bodies with instrumentation and methods similar to those used in association with the lumbar spine but modified for use in the cervical spine. Implant 200A may, for example, have a leading end 202A formed to have a shape of approximately one-half a first circle from side to side. Trailing end 204A preferably may be formed as an arc of a second circle from side to side that intersects the curvature of leading end 202A from side to side. The radius of the second circle associated with trailing end 204A is preferably greater than the radius of the first circle associated with leading end 202A.

Fig. 20 shows another preferred embodiment of the present invention of an implant made of a material other than bone for use in the cervical spine generally referred to by the numeral 200B. Implant 200B is preferably configured to conform to the shape of implantation space 60 formed in the endplates of adjacent cervical vertebral bodies. Implant 200B may, for example, have a leading end 202B formed to have a shape of approximately one-half a first circle from side to side. Trailing end 204B preferably may be formed as an arc of a second circle from side to side that intersects the curvature of leading end 202B from side to side. The radius of the second circle associated with trailing end 204B is preferably greater than the radius of the first circle associated with leading end 202B.

Figs. 21-26 show an implant 300A preferably made of bone or a bone composite material in accordance with another preferred embodiment of the present invention adapted for use from the anterior approach to the spine. Fig. 21 shows a rear perspective view of implant 300A. Implant 300A includes at least two members 300A', 300A'' that are adapted to be placed side by side with

one another. Member 300A' is preferably, but need not be a mirror image of member 300A''. The description of member 300A' is equally applicable to member 300A''. Member 300A' has a leading portion 302A' for insertion first into the disc space between two adjacent vertebral bodies and a trailing portion 304A' opposite leading portion 302A'. Member 300A' has a top 306A', a bottom 308A', an interior side 310A', and an exterior facing side 312A' opposite interior facing side 310A'. As used herein, the phrase "interior side" describes the side of the member adapted to be orientated toward the interior side of another member when a pair of members are inserted side by side into the disc space. In a preferred embodiment, interior side 310A' includes at least a portion of the medullary canal of the bone ring.

Leading portions 302A', 302A'' of each member 300A', 300A'', respectively, form leading end 302A of implant 300A when the members are placed side by side to one another. Leading end 302A of implant 300A is preferably configured in the shape of one-half a first circle from side to side. Trailing end 304A, composed of trailing portions 304A', 304A'' when members 300A', 300A'' are placed side by side to one another, may, but need not be formed as an arc of a second circle side to side having a radius greater than a radius of the first circle associated with leading end 302A of implant 300A.

Member 300A' is placed side by side with member 300A'' so that the portion of the medullary canal of interior side 310A' of each member are adjacent one another to form a passage 314A through implant 300A. Preferably passage 314A is adapted to hold bone growth promoting material to permit for the growth of bone from vertebral body to vertebral body through passage 314A. Member 300A' preferably has a maximum width W that is less than approximately one-half the width of the adjacent vertebral bodies into which the member is adapted to be inserted. Also, the combined width of both members 300A', 300A'' is preferably greater than one-half the width of the adjacent vertebral bodies into which the members are adapted to be inserted.

Members 300A', 300A'' provide the added advantage in that each member can be inserted through a smaller space than a single larger implant, to achieve the same effect as the larger implant.

Figs. 27-32 show an implant 300B made of a material other than bone in accordance with another preferred embodiment of the present invention adapted



for use from the anterior approach to the spine. Fig. 27 shows a rear perspective view of implant 300B. Implant 300B includes at least two members 300B', 300B'' that are adapted to be placed side by side with one another. Member 300B' is preferably, but need not be a mirror image of member 300B''. The description of member 300B' is equally applicable to member 300B''. Member 300B' has a leading portion 302B' for insertion first into the disc space between two adjacent vertebral bodies and a trailing portion 304B' opposite leading portion 302B'. Member 300B' has a top 306B', a bottom 308B', an interior side 310B', and an exterior facing side 312B' opposite interior facing side 310B'.

Leading portions 302B', 302B'' of each member 300B', 300B'', respectively, form leading end 302B of implant 300B when the members are placed side by side to one another. Leading end 302B of implant 300B is preferably configured in the shape of one-half a first circle from side to side. Trailing end 304B, composed of trailing portions 304B', 304B'' when members 300B', 300B'' are placed side by side to one another, may, but need not be formed as an arc of a second circle side to side having a radius greater than a radius of the first circle associated with leading end 302B of implant 300B.

Member 300' is placed side by side with member 300B'' so that a portion of interior side 310B' of each member are adjacent one another. Top 306B' and bottom 308B' preferably have at least one opening 314B' passing therethrough between leading and trailing portions 302B', 304B', respectively, and sides 310B', 312B'. Openings 314B' are adapted to hold bone growth promoting material to permit for the growth of bone from vertebral body to vertebral body through openings 314B. Interior side 310B' may also include at least one opening 314B' passing therethrough configured to permit bone growth between and into adjacent members 300B', 300B''. Member 300B' preferably has a maximum width W that is less than approximately one-half the width of the adjacent vertebral bodies into which the member is adapted to be inserted. Also, the combined width of both members 300B', 300B'' is preferably greater than one-half the width of the adjacent vertebral bodies into which the members are adapted to be inserted.

Members 300B', 300B'' provide the added advantage in that each member can be inserted through a smaller space than a single larger implant, to achieve the same effect as the larger implant.

Fig. 33 shows an implant 400A in accordance with another preferred embodiment of the present invention adapted for use from an anterior approach to the spine. Implant 400A is similar to implant 100A and has a leading end 402A that is shaped as approximately one-half a first circle. Implant 400A is adapted to have a maximum width between sides 410A, 412A that is less than one-half of the width of the adjacent vertebral bodies into which implant 400A is adapted to be inserted. Trailing end 404A forms an arc of a second circle having a radius that is substantially greater than the radius of the first circle associated with leading end 402A. Implants 400A can be made of bone, a bone composite, or a material other than bone.

Fig. 34 shows an implant 500A in accordance with another preferred embodiment of the present invention adapted for use from an anterior approach to the spine. Implant 500A is similar to implant 400A except that both leading end 502A and trailing end 504A are preferably in the shape of a half circle side to side. Implants 500A can be made of bone, a bone composite, or a material other than bone.

Fig. 35 shows an implant 600A in accordance with another preferred embodiment of the present invention adapted for use from a posterior approach to the spine. Implant 600A is similar to implant 400A except that trailing end 604A is preferably at least in part straight from side to side. Implants 600A can be made of bone, a bone composite, or a material other than bone.

Figs. 36-42 show an implant 700A made of bone or a bone composite in accordance with another embodiment of the present invention. Implant 700A is similar to implant 100A and has a leading end 702A in the shape of approximately one-half a first circle A and a trailing end 704A formed as an arc of a second circle C. Implant 700A preferably includes straight portions 711A, 713A along at least a portion of sides 710A, 712A, respectively, that are preferably parallel to each other along lines P. Implant 700A also preferably includes a curved transition from each straight portion 711A, 713A of sides 710A, 712A, respectively, to trailing end 704A to form rounded portions 715A, 717A, respectively. Rounded portion 715A, 717A may be an arc of a third circle E that preferably has a radius less than the radii of circle A associated with leading end 702A and/or circle C associated with trailing end 704A.

In a preferred embodiment, implant 700A may be machined so as to be adapted to receive through bone screw receiving holes 720A at trailing end 704A at least a pair of opposed appropriately sized bone screws 722A preferably, but not necessarily, made of cortical bone. Bone engaging screws 722A may be aligned or offset from each other. At least one screw 722A engages each of the vertebral bodies adjacent a disc space to be fused and into which implant 700A is implanted. A purpose of the bone screws is to rigidly secure the implant within the vertebral segment. A further purpose is to pull each of the adjacent vertebral bodies toward the implant and towards each other. Trailing end 704A of implant 700A preferably includes a recess 724A having bone screw receiving holes 720A therein and an opening 726A configured to cooperatively receive a locking cap 728A adapted to lock at least one bone screw 722A to implant 700A.

As shown in Fig. 41, implant 700A is preferably further machined and adapted to receive a lock 728A, preferably made of cortical bone, at trailing end 704A for securing bone engaging screws 722A therein and preventing the screws from backing out. Locking cap 728A has a top 730A, a stem 732A, and a tool engagement area 734A. In use, locking cap cooperatively engages trailing end 704A of implant 700A at opening 726A to lock at least one bone screw to implant 700A. If desired, locking cap 728A may include a thread on stem 732A to allow locking cap 728A to rotationally engage implant 700A.

Fig. 42 shows another preferred embodiment of a locking cap, generally referred to by the numeral 736A. Locking cap 736A includes a top 738A having a thread 740A at its outer perimeter that is adapted to cooperatively engage a corresponding threaded recess in the implant.

The bone implant, bone screws, and/or locks can be made of a bioresorbable material, including but not limited to cortical bone, plastics and composite plastics. Suitable plastics may include those comprising lactides, galactides, glycolide, caprolactone, trimethylene carbonate, or dioxanone in various polymers, and/or combinations thereof.

Figs. 43-49 show an implant 700B made of a material other than bone in accordance with another embodiment of the present invention. Implant 700B is similar to implant 100B and has a leading end 702B in the shape of approximately one-half a first circle A and a trailing end 704B formed as an arc of a second circle C. Implant 700B preferably includes straight portions 711B, 713B

along at least a portion of sides 710B, 712B, respectively, that are preferably parallel to each other along lines P. Implant 700B also preferably includes a curved transition from each straight portion 711B, 713B of sides 710B, 712B, respectively, to trailing end 704B to form rounded portions 715B, 717B, respectively. Rounded portion 715B, 717B may be an arc of a third circle E that preferably has a radius less than the radii of circle A associated with leading end 702B and/or circle C associated with trailing end 704B.

In a preferred embodiment, implant 700B may be adapted to receive through bone screw receiving holes 720B at trailing end 704B at least a pair of opposed appropriately sized bone screws 722B. Bone engaging screws 722B may be aligned or offset from each other. At least one screw 722B engages each of the vertebral bodies adjacent a disc space to be fused and into which implant 700B is implanted. Trailing end 704B of implant 700B preferably includes a recess 724B having bone screw receiving holes 720B therein and an opening 726B configured to cooperatively receive a locking cap 728B adapted to lock at least one bone screw 722B to implant 700B.

As shown in Fig. 48, implant 700B is preferably adapted to receive a lock 728B at trailing end 704B for securing bone engaging screws 722B therein and preventing the screws from backing out. Locking cap 728B has a top 730B, a stem 732B, and a tool engagement area 734B. In use, locking cap cooperatively engages trailing end 704B of implant 700B at opening 726B to lock at least one bone screw to implant 700B. If desired, locking cap 728B may include a thread on stem 732B to allow locking cap 728B to rotationally engage implant 700B.

Fig. 49 shows another preferred embodiment of a locking cap, generally referred to by the numeral 736B. Locking cap 736B includes a top 738B having a thread 740B at its outer perimeter that is adapted to cooperatively engage a corresponding threaded recess in the implant.

Implant 700B, bone screws 722B, and/or locks 728B, 736B can be made of a bioresorbable material, including but not limited to plastics and composite plastics. Suitable plastics may include those comprising lactides, galactides, glycolide, caprolactone, trimethylene carbonate, or dioxanone in various polymers, and/or combinations thereof.

By way of example only and not limitation, for use in the lumbar spine, the implants of the present invention may have a depth of approximately, 28-36 mm,

a width of approximately, 30-38 mm, and a height (max) of approximately 8-20 mm. The radius of curvature of the leading end may be approximately 15-19 mm and the radius of curvature of the trailing end may be approximately 20-30 mm.

In any of the embodiments of the present invention, the implant may include, be made of, treated, coated, filled, used in combination with, or have an opening, a hollow, or a passage for containing artificial or naturally occurring materials and/or substances suitable for implantation in the human spine. These materials and/or substances include any source of osteogenesis, bone growth promoting materials, bone, bone derived substances or products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic proteins, hydroxyapatite, genes coding for the production of bone, and bone including, but not limited to, cortical bone. The implant can include at least in part of materials that are bioabsorbable and/or resorbable in the body such as bone and/or bone growth promoting materials. The implant of the present invention can be formed of a porous material or can be formed of a material that intrinsically participates in the growth of bone from one of adjacent vertebral bodies to the other of adjacent vertebral bodies. Where such implants are for posterior implantation, the trailing ends of such implants may be treated with, coated with, or used in combination with chemical substances to inhibit scar tissue formation in the spinal canal. The implant of the present invention may be modified, or used in combination with materials to make it antibacterial, such as, but not limited to, electroplating or plasma spraying with silver ions or other substance. At least a portion of the implant may be treated to promote bone ingrowth between the implant and the adjacent vertebral bodies. The implant of the present invention may be used in combination with a spinal fixation implant such as any object, regardless of material, that can be inserted into any portion of the spine, such as but not limited to interbody spinal implants, structural bone grafts, mesh, cages, spacers, staples, bone screws, plates, rods, tethers of synthetic cords or wires, or other spinal fixation hardware

While the shapes of the various aspects of the implant have been described precisely, the scope of the present invention is not so limited and it is readily anticipated that the contours may be interrupted by minor irregularities such as for example only for the purpose of engaging the bone, encouraging the ingrowth or through growth of bone.

While specific innovative features were presented in reference to specific examples, they are just examples, and it should be understood that various combinations of these innovative features beyond those specifically shown are taught such that they may now be easily alternatively combined and are hereby anticipated and claimed.

What is claimed is:

1. An interbody spinal implant made of cortical bone for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect and a depth therebetween, said implant comprising:
  - a leading end for insertion first into the disc space and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end;
  - opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in part within and across the height of the disc space to contact and support the adjacent vertebral bodies, said upper and lower portions being non-arcuate along at least a portion of the length of said implant; and
  - opposite sides between said upper portion and said lower portion, and between said leading and trailing ends, said opposite sides defining a width of said implant, at least one of said opposite sides being at least in part straight along at least a portion of the length of said implant, said leading end configured in the shape of approximately one half of a circle from one of said opposite sides to another of said opposite sides, the circle having a diameter generally equal to the width of said implant;
  - said implant being manufactured from a bone ring obtained from a major long bone of a human having a medullary canal, said implant including at least a portion of the medullary canal passing through said upper and lower portions to form at least a portion of a passage adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through said passage.
2. The implant of claim 1, wherein said implant has a maximum width between said opposite sides that is greater than one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted.

3. The implant of claim 1, wherein said implant has a maximum width between said opposite sides that is less than one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted.
4. The implant of claim 3, wherein said implant is adapted to be inserted side by side a second of said implant into the disc space between the adjacent vertebral bodies.
5. The implant of claim 1, wherein at least a portion of said leading end has a reduced height to facilitate insertion of said implant between the two adjacent vertebral bodies.
6. The implant of claim 1, wherein said trailing end is adapted to conform from side to side to at least a portion of the peripheral contour of at least one of the anterior and posterior aspects of the vertebral bodies adjacent a disc space into which said implant is inserted.
7. The implant of claim 1, wherein said passage is between said opposite sides of said implant.
8. The implant of claim 1, wherein said passage intersects at least one of said opposite sides.
9. The implant of claim 1, wherein said passage is between said leading and trailing ends of said implant.
10. The implant of claim 1, wherein said implant has a mid-longitudinal axis along the length, at least one of said opposite sides being at least in part oriented generally parallel to the mid-longitudinal axis of said implant.
11. The implant of claim 1, wherein said opposite sides are at least in part generally parallel one another.
12. The implant of claim 1, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.
13. The implant of claim 1, wherein said implant has a maximum length less than and approximating the posterior to anterior depth of the vertebral bodies.
14. The implant of claim 1, further comprising a bone engaging surface formed on the exterior of at least said upper and lower portions for engaging the adjacent vertebral bodies, said bone engaging surface including at least



- one of a protrusion, a ratchet, a spike, a spline, surface roughenings, and knurling.
15. The implant of claim 1, wherein said implant includes at least two members, each member having a leading portion, a trailing portion, a top, a bottom, and at least one side, each member being adapted to be placed side by side with another of said members, said leading portion of said members forming said leading end of said implant when placed side by side.
  16. The implant of claim 15, wherein said implant includes two of said members, each member being a mirror image of the other.
  17. The implant of claim 15, wherein each member includes at least a portion of said passage.
  18. The implant of claim 1, wherein said implant comprises at least in part of a bone growth promoting material.
  19. The implant of claim 18, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
  20. The implant of claim 1, in combination with a bone growth promoting material.
  21. The implant of claim 20, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
  22. The implant of claim 1, wherein said implant is treated with a bone growth promoting substance.
  23. The implant of claim 1, wherein said implant is at least in part resorbable.
  24. The implant of claim 1, in combination with a chemical substance adapted to inhibit scar formation.
  25. The implant of claim 1, in combination with an antimicrobial material.
  26. The implant of claim 1, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.

27. The implant of claim 1, further in combination with at least one spinal fixation implant.
28. The implant of claim 1, wherein said trailing end is adapted to receive at least one bone screw adapted to engage at least one vertebral body when inserted through said implant.
29. The implant of claim 28, further comprising a lock for locking at least one bone screw to said implant.
30. The implant of claim 29, wherein said lock is made of one of cortical bone and a bioresorbable material.
31. The implant of claim 28, wherein said screw is made of one of cortical bone and a bioresorbable material.
32. An interbody spinal implant made of cortical bone for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect and a depth therebetween, said implant comprising:
  - a leading end for insertion first into the disc space and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end;
  - opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in part within and across the height of the disc space to contact and support the adjacent vertebral bodies;
  - said implant having a maximum width that is greater than one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted, said leading end configured in the shape of approximately one half of a first circle along the width of said implant, said trailing end having a radius of curvature of a second circle along the width of said implant, the second circle having a radius greater than the radius of the first circle; and
  - said implant being manufactured from a bone ring obtained from a major long bone of a human having a medullary canal, said implant including at least a portion of the medullary canal passing through said upper and lower portions to form a passage adapted to hold bone growth

- promoting material for permitting for the growth of bone from vertebral body to vertebral body through said passage.
33. The implant of claim 32, wherein said leading end and said trailing end of said implant intersect at diametrically opposite points of the implant.
  34. The implant of claim 32, wherein said width of said implant is approximately equal to the diameter of the first circle.
  35. The implant of claim 32, wherein said implant has a height from said upper portion to said lower portion, the height of said implant being less than the maximum width of said implant.
  36. The implant of claim 32, wherein at least a portion of said leading end has a reduced height to facilitate insertion of said implant between the two adjacent vertebral bodies.
  37. The implant of claim 32, wherein said trailing end is adapted to conform from side to side to at least a portion of the peripheral contour of at least one of the anterior and posterior aspects of the vertebral bodies adjacent a disc space into which said implant is inserted.
  38. The implant of claim 32, wherein said implant has a perimeter, said passage being within said perimeter of said implant.
  39. The implant of claim 32, wherein said implant has a perimeter, said passage intersecting at least a portion of said perimeter.
  40. The implant of claim 32, wherein said passage is between said leading and trailing ends of said implant.
  41. The implant of claim 32, further comprising opposite sides between said leading end and said trailing end.
  42. The implant of claim 41, wherein at least one of said opposite sides is at least in part straight along at least a portion of the length of said implant.
  43. The implant of claim 41, wherein said implant has a mid-longitudinal axis along the length, at least one of said opposite sides being at least in part oriented generally parallel to the mid-longitudinal axis of said implant.
  44. The implant of claim 41, wherein said opposite sides are at least in part generally parallel one another.
  45. The implant of claim 32, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to

- leading end for allowing angulation of the adjacent vertebral bodies relative to each other.
46. The implant of claim 32, wherein said implant has a maximum length less than and approximating the posterior to anterior depth of the vertebral bodies.
47. The implant of claim 32, further comprising a bone engaging surface formed on the exterior of at least said upper and lower portions for engaging the adjacent vertebral bodies, said bone engaging surface including at least one of a protrusion, a ratchet, a spike, a spline, surface roughenings, and knurling.
48. The implant of claim 32, wherein said implant includes at least two members, each member having a leading portion, a trailing portion, a top, a bottom, and at least one side, each member being adapted to be placed side by side with another of said members, said leading portion of said members forming said leading end of said implant when placed side by side.
49. The implant of claim 47, wherein said implant includes two of said members, each member being a mirror image of the other.
50. The implant of claim 48, wherein each member includes at least a portion of said passage.
51. The implant of claim 32, wherein said implant comprises at least in part of a bone growth promoting material.
52. The implant of claim 51, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
53. The implant of claim 32, in combination with a bone growth promoting material.
54. The implant of claim 53, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
55. The implant of claim 32, wherein said implant is treated with a bone growth promoting substance.

56. The implant of claim 32, wherein said implant is at least in part resorbable.
57. The implant of claim 32, in combination with a chemical substance adapted to inhibit scar formation.
58. The implant of claim 32, in combination with an antimicrobial material.
59. The implant of claim 32, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.
60. The implant of claim 32, further in combination with at least one spinal fixation implant.
61. The implant of claim 40, further comprising a curved transition between at least one of said opposite sides and said trailing end, said curved transition forming at least part of an arc of a circle.
62. The implant of claim 32, wherein said trailing end is adapted to receive at least one bone screw adapted to engage at least one vertebral body when inserted through said implant.
63. The implant of claim 62, further comprising a lock for locking at least one bone screw to said implant.
64. The implant of claim 63, wherein said lock is made of one of cortical bone and a bioresorbable material.
65. The implant of claim 62, wherein said screw is made of one of cortical bone and a bioresorbable material.
66. An interbody spinal implant made of a bone composite material for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect and a depth therebetween, said implant comprising:
  - a leading end for insertion first into the disc space and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end;
  - opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in part within and across the height of the disc space to contact and support the adjacent vertebral bodies, said upper and lower portions being non-arcuate along at least a portion of the length of said implant;

opposite sides between said upper portion and said lower portion, and between said leading and trailing ends, said opposite sides defining a width of said implant, at least one of said opposite sides being at least in part straight along at least a portion of the length of said implant, said leading end configured in the shape of approximately one half a circle from one of said opposite sides to another of said opposite sides, the circle having a diameter generally equal to the width of said implant; and

said implant being manufactured from a bone composite material, said upper and lower portions of said implant including at least one opening in communication with one another to form at least a portion of a passage adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through said passage.

67. The implant of claim 66, wherein said bone composite material includes at least one of cortical bone fibers, bone filaments, bone particles and bone dust.
68. The implant of claim 66, further comprising a binding material.
69. The implant of claim 59, wherein said binding material is at least one of bioactive and bioresorbable.
70. The implant of claim 66, wherein said implant has a maximum width between said opposite sides that is greater than one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted,
71. The implant of claim 66, wherein said implant has a maximum width between said opposite sides that is less than one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted.
72. The implant of claim 71, wherein said implant is adapted to be inserted side by side a second of said implant into the disc space between the adjacent vertebral bodies.
73. The implant of claim 66, wherein at least a portion of said leading end is has a reduced height to facilitate insertion of said implant between the two adjacent vertebral bodies.
74. The implant of claim 66, wherein said trailing end is adapted to conform from side to side to at least a portion of the peripheral contour of at least

- one of the anterior and posterior aspects of the vertebral bodies adjacent a disc space into which said implant is inserted.
75. The implant of claim 66, wherein said passage is between said opposite sides of said implant.
  76. The implant of claim 66, wherein said passage intersects at least one of said opposite sides of said implant.
  77. The implant of claim 66, wherein said passage is between said leading and trailing ends of said implant.
  78. The implant of claim 66, wherein said implant has a mid-longitudinal axis, at least one of said opposite sides being at least in part oriented generally parallel to the mid-longitudinal axis of said implant.
  79. The implant of claim 66, wherein said opposite sides are at least in part generally parallel one another.
  80. The implant of claim 66, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.
  81. The implant of claim 66, wherein said implant has a maximum length less than and approximating the posterior to anterior depth of the vertebral bodies.
  82. The implant of claim 66, further comprising a bone engaging surface formed on the exterior of at least said upper and lower portions for engaging the adjacent vertebral bodies, said bone engaging surface including at least one of a protrusion, a ratchet, a spike, a spline, surface roughenings, and knurling.
  83. The implant of claim 66, wherein said implant includes at least two members, each member having a leading portion, a trailing portion, a top, a bottom, and at least one side, each member being adapted to be placed side by side with another of said members, said leading portion of said members forming said leading end of said implant when placed side by side.
  84. The implant of claim 83, wherein said implant includes two of said members, each member being a mirror image of the other.

85. The implant of claim 83, wherein each member includes at least a portion of said passage.
86. The implant of claim 66, wherein said implant comprises at least in part of a bone growth promoting material.
87. The implant of claim 86, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
88. The implant of claim 66, in combination with a bone growth promoting material.
89. The implant of claim 88, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
90. The implant of claim 66, wherein said implant is treated with a bone growth promoting substance.
91. The implant of claim 66, wherein said implant is at least in part resorbable.
92. The implant of claim 66, in combination with a chemical substance adapted to inhibit scar formation.
93. The implant of claim 66, in combination with an antimicrobial material.
94. The implant of claim 66, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.
95. The implant of claim 66, further in combination with at least one spinal fixation implant.
96. The implant of claim 66, wherein said trailing end is adapted to receive at least one bone screw adapted to engage at least one vertebral body when inserted through said implant.
97. The implant of claim 96, further comprising a lock for locking at least one bone screw to said implant.
98. The implant of claim 97, wherein said lock is made of one of cortical bone and a bioresorbable material.
99. The implant of claim 96, wherein said screw is made of one of cortical bone and a bioresorbable material.



100. An interbody spinal implant made of a bone composite material for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect and a depth therebetween, said implant comprising:
- a leading end for insertion first into the disc space and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end;
  - opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in part within and across the height of the disc space to contact and support the adjacent vertebral bodies;
  - said implant having a maximum width that is greater than one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted, said leading end configured in the shape of approximately one half of a first circle along the width of said implant, said trailing end having a radius of curvature of a second circle along the width of said implant, the second circle having a radius greater than the radius of the first circle; and
  - said implant being manufactured from a bone composite material, said upper and lower portions of said implant including at least one opening in communication with one another to form a passage adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through said passage.
101. The implant of claim 100, wherein said bone composite material includes at least one of cortical bone fibers, bone filaments, bone particles and bone dust.
102. The implant of claim 100, further comprising a binding material.
103. The implant of claim 102, wherein said binding material is at least one of bioactive and bioresorbable.
104. The implant of claim 100, wherein said leading end and said trailing end of said implant intersect at diametrically opposite points of the implant.
105. The implant of claim 100, wherein said width of said implant is approximately equal to the diameter of the first circle.

106. The implant of claim 100, wherein said implant has a height from said upper portion to said lower portion the height of said implant is less than the maximum width of said implant.
107. The implant of claim 100, wherein at least a portion of said leading end has a reduced height to facilitate insertion of said implant between the two adjacent vertebral bodies.
108. The implant of claim 100, wherein said trailing end is adapted to conform from side to side to at least a portion of the peripheral contour of at least one of the anterior and posterior aspects of the vertebral bodies adjacent a disc space into which said implant is inserted.
109. The implant of claim 100, wherein implant has a perimeter and said passage is at least in part with said perimeter of said implant.
110. The implant of claim 100, wherein said implant has a perimeter, said passage intersecting at least a portion of said perimeter of said implant.
111. The implant of claim 100, wherein said passage is between said leading and trailing ends of said implant.
112. The implant of claim 100, further comprising opposite sides between said leading end and said trailing end.
113. The implant of claim 112, wherein at least one of said opposite sides is at least in part straight along at least a portion of the length of said implant.
114. The implant of claim 112, wherein said implant has a mid-longitudinal axis along the length, at least one of said opposite sides being at least in part oriented generally parallel to the mid-longitudinal axis of said implant.
115. The implant of claim 112, wherein said opposite sides are at least in part generally parallel one another.
116. The implant of claim 100, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.
117. The implant of claim 100, wherein said implant has a maximum length less than and approximating the posterior to anterior depth of the vertebral bodies.
118. The implant of claim 100, further comprising a bone engaging surface formed on the exterior of at least said upper and lower portions for

- engaging the adjacent vertebral bodies, said bone engaging surface including at least one of a protrusion, a ratchet, a spike, a spline, surface roughenings, and knurling.
119. The implant of claim 100, wherein said implant includes at least two members, each member having a leading portion, a trailing portion, a top, a bottom, and at least one side, each member being adapted to be placed side by side with another of said members, said leading portion of said members forming said leading end of said implant when placed side by side.
120. The implant of claim 119, wherein said implant includes two of said members, each member being a mirror image of the other.
121. The implant of claim 119, wherein each member includes at least a portion of said passage.
122. The implant of claim 100, wherein said implant comprises at least in part of a bone growth promoting material.
123. The implant of claim 122, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
124. The implant of claim 100, in combination with a bone growth promoting material.
125. The implant of claim 124, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
126. The implant of claim 100, wherein said implant is treated with a bone growth promoting substance.
127. The implant of claim 100, wherein said implant is at least in part resorbable.
128. The implant of claim 100, in combination with a chemical substance adapted to inhibit scar formation.
129. The implant of claim 100, in combination with an antimicrobial material.

130. The implant of claim 100, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.
131. The implant of claim 100, further in combination with at least one spinal fixation implant.
132. The implant of claim 111, further comprising a curved transition between at least one of said opposite sides and said trailing end, said curved transition forming at least part of an arc of a circle.
133. The implant of claim 100, wherein said trailing end is adapted to receive at least one bone screw adapted to engage at least one vertebral body when inserted through said implant.
134. The implant of claim 133, further comprising a lock for locking at least one bone screw to said implant.
135. The implant of claim 134, wherein said lock is made of one of cortical bone and a bioresorbable material.
136. The implant of claim 133, wherein said screw is made of one of cortical bone and a bioresorbable material.
137. An artificial interbody spinal implant for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect and a depth therebetween, said implant comprising:
  - a leading end for insertion first into the disc space and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end;
  - opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in part within and across the height of the disc space to contact and support the adjacent vertebral bodies, said upper and lower portions defining a height of said implant, said upper and lower portions being non-arcuate along at least a portion of the length of said implant; and
  - opposite sides between said upper portion and said lower portion, and between said leading and trailing ends, said opposite sides defining a width of said implant, at least one of said opposite sides being at least in

part straight along at least a portion of the length of said implant, said leading end configured in the shape of approximately one half of a circle from one of said opposite sides to another one of said opposite sides, the circle having a diameter generally equal to the width of said implant, the width of said implant being greater than the height of said implant;

said implant being manufactured from a material other than bone, said upper and lower portions of said implant including at least one opening in communication with one another and adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through said implant.

138. The implant of claim 137, wherein said implant has a maximum width between said opposite sides that is greater than one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted.
139. The implant of claim 137, wherein said implant has a maximum width between said opposite sides that is less than one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted.
140. The implant of claim 139, wherein said implant is adapted to be inserted side by side a second of said implant into the disc space between the adjacent vertebral bodies.
141. The implant of claim 137, wherein at least a portion of said leading end has a reduced height to facilitate insertion of said implant between the two adjacent vertebral bodies.
142. The implant of claim 137, wherein said trailing end is adapted to conform from side to side to at least a portion of the peripheral contour of at least one of the anterior and posterior aspects of the vertebral bodies adjacent a disc space into which said implant is inserted.
143. The implant of claim 137, wherein said trailing end has a radius of curvature of a second circle from side to side.
144. The implant of claim 143, wherein the radius of curvature said trailing end is greater than the radius of curvature of the leading end of said implant.
145. The implant of claim 137, wherein said at least one opening is between said opposite sides of said implant.

146. The implant of claim 137, wherein said at least one opening intersects at least one of said opposite sides.
147. The implant of claim 137, wherein said at least one opening is between said leading and trailing ends of said implant.
148. The implant of claim 137, wherein said implant has a mid-longitudinal axis along the length, at least one of said opposite sides being at least in part oriented generally parallel to the mid-longitudinal axis of said implant.
149. The implant of claim 137, wherein said opposite sides are at least in part generally parallel one another.
150. The implant of claim 137, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.
151. The implant of claim 137, wherein said implant has a maximum length less than and approximating the posterior to anterior depth of the vertebral bodies.
152. The implant of claim 137, further comprising a bone engaging surface formed on the exterior of at least said upper and lower portions for engaging the adjacent vertebral bodies, said bone engaging surface including at least one of a protrusion, a ratchet, a spike, a spline, surface roughenings, and knurling.
153. The implant of claim 137, wherein said implant includes at least two members, each member having a leading portion, a trailing portion, a top, a bottom, and at least one side, each member being adapted to be placed side by side with another of said members, said leading portion of said members forming said leading end of said implant when placed side by side.
154. The implant of claim 153, wherein said implant includes two of said members, each member being a mirror image of the other.
155. The implant of claim 153, wherein each member includes at least a portion of said at least one opening.
156. The implant of claim 137, in combination with a bone growth promoting material.

157. The implant of claim 156, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
158. The implant of claim 137, wherein said implant is treated with a bone growth promoting substance.
159. The implant of claim 137, wherein said implant is at least in part resorbable.
160. The implant of claim 137, in combination with a chemical substance adapted to inhibit scar formation.
161. The implant of claim 137, in combination with an antimicrobial material.
162. The implant of claim 137, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.
163. The implant of claim 137, in combination with at least one spinal fixation implant.
164. The implant of claim 137, wherein said trailing end is adapted to receive at least one bone screw adapted to engage at least one vertebral body when inserted through said implant.
165. The implant of claim 164, further comprising a lock for locking at least one bone screw to said implant.
166. An artificial interbody spinal implant for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect and a depth therebetween, said implant comprising:
  - a leading end for insertion first into the disc space and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end;
  - opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in part within and across the height of the disc space to contact and support the adjacent vertebral bodies;
  - said implant having a maximum width that is greater than one-half of the width of the adjacent vertebral bodies into which said implant is

adapted to be inserted, said leading end configured in the shape of approximately one half of a first circle along the width of said implant, said trailing end having a radius of curvature of a second circle along the width of said implant, the second circle having a radius greater than the radius of the first circle; and

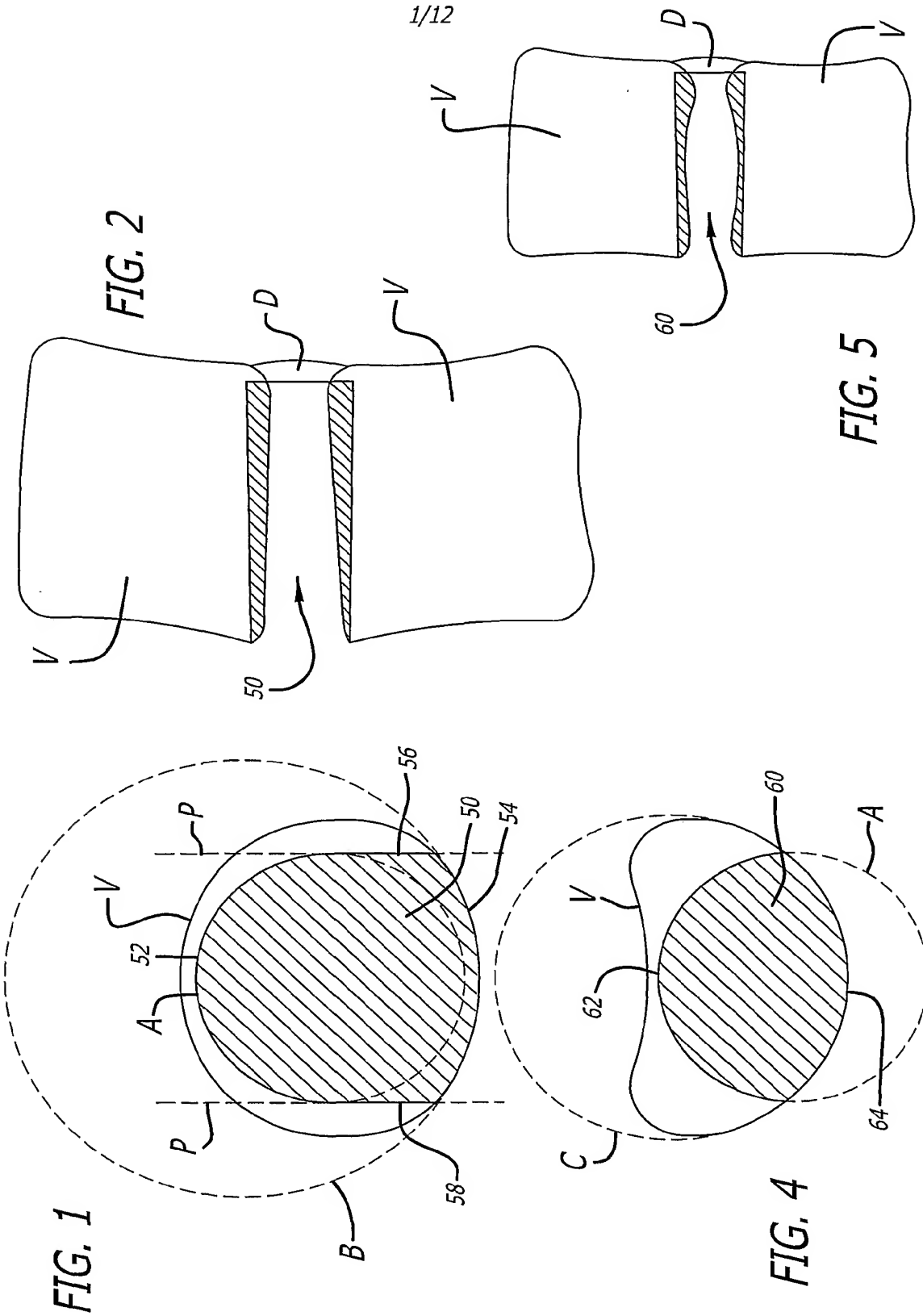
said implant being manufactured from a material other than bone, said upper and lower portions of said implant including at least one opening in communication with one another and adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through said implant.

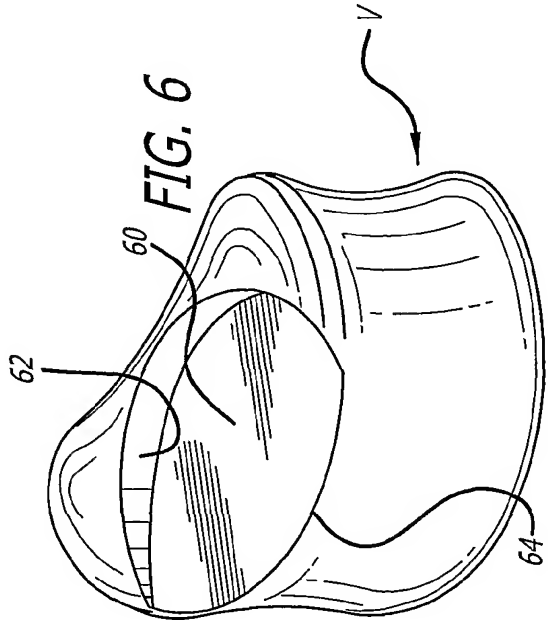
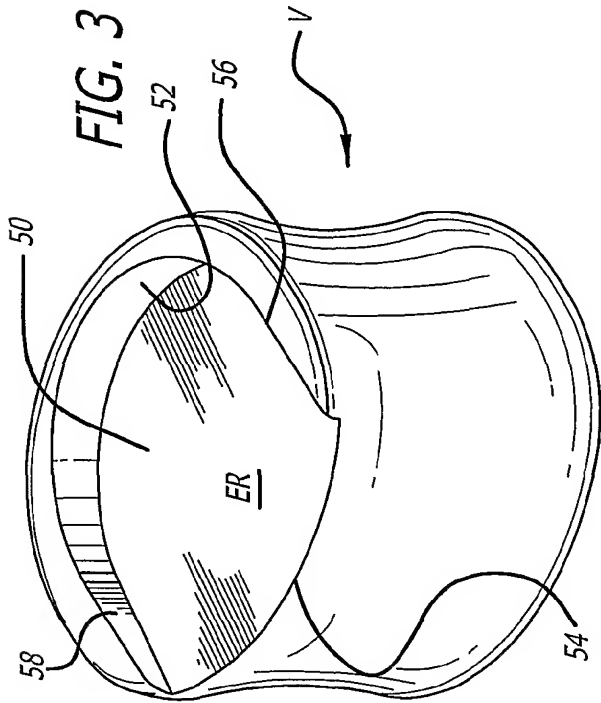
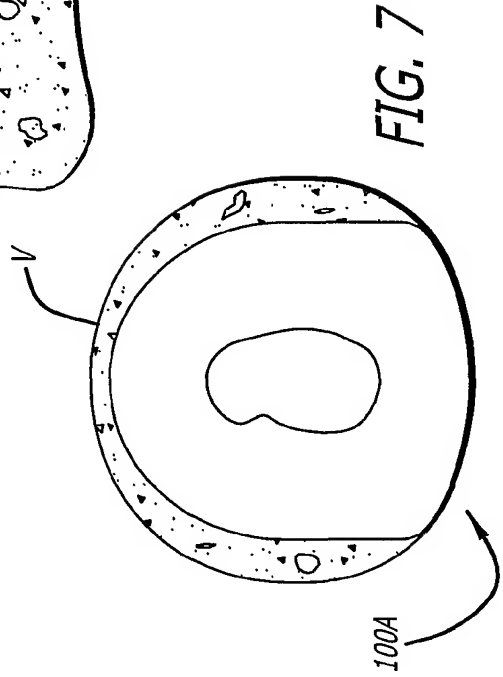
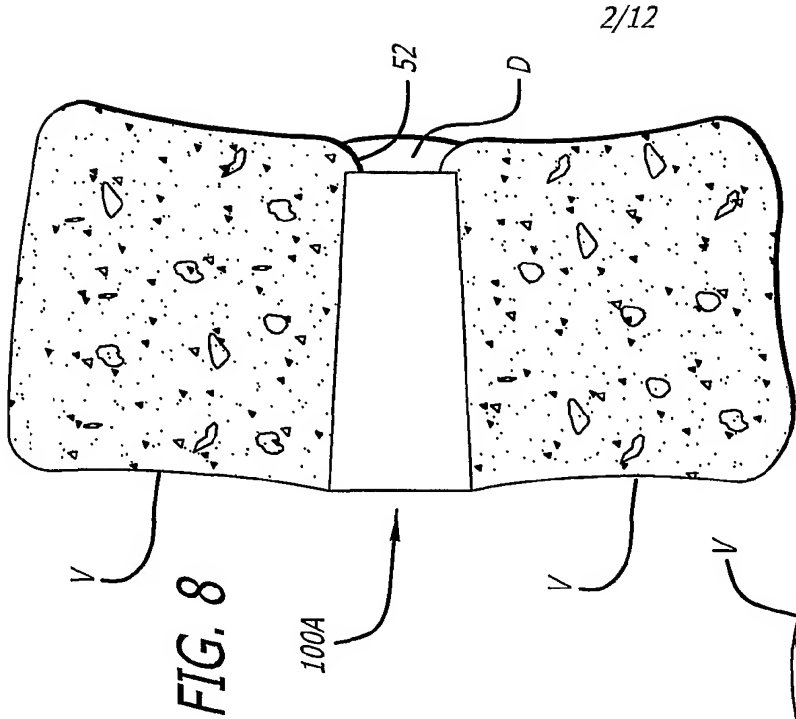
167. The implant of claim 166, wherein said leading end and said trailing end of said implant intersect at diametrically opposite points of said implant.
168. The implant of claim 166, wherein said width of said implant is approximately equal to the diameter of the first circle.
169. The implant of claim 166, wherein said implant has a height from said upper portion to said lower portion, the height of said implant being less than the maximum width of said implant.
170. The implant of claim 166, wherein at least a portion of said leading end has a reduced height to facilitate insertion of said implant between the two adjacent vertebral bodies.
171. The implant of claim 166, wherein said trailing end is adapted to conform from side to side to at least a portion of the peripheral contour of the anterior aspect of the vertebral bodies adjacent a disc space into which said implant is inserted.
172. The implant of claim 166, wherein said implant has a perimeter, said at least one opening being within said perimeter of said implant.
173. The implant of claim 166, wherein said implant has a perimeter, said at least one opening intersecting at least a portion of said perimeter of said implant.
174. The implant of claim 166, wherein said at least one opening is between said leading and trailing ends of said implant.
175. The implant of claim 166, further comprising opposite sides between said leading end and said trailing end.

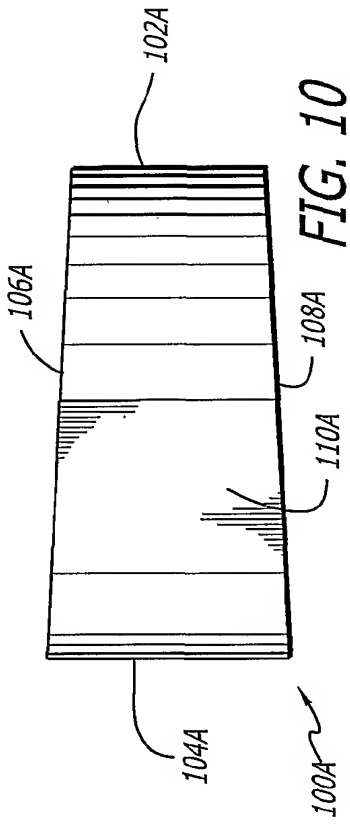
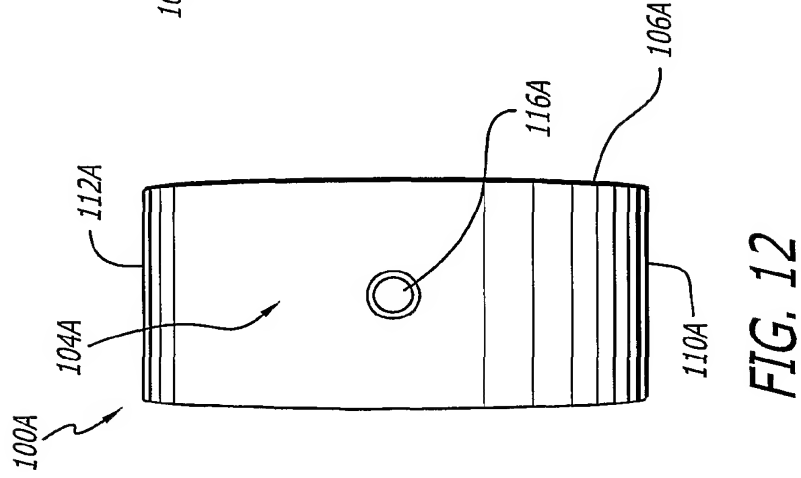
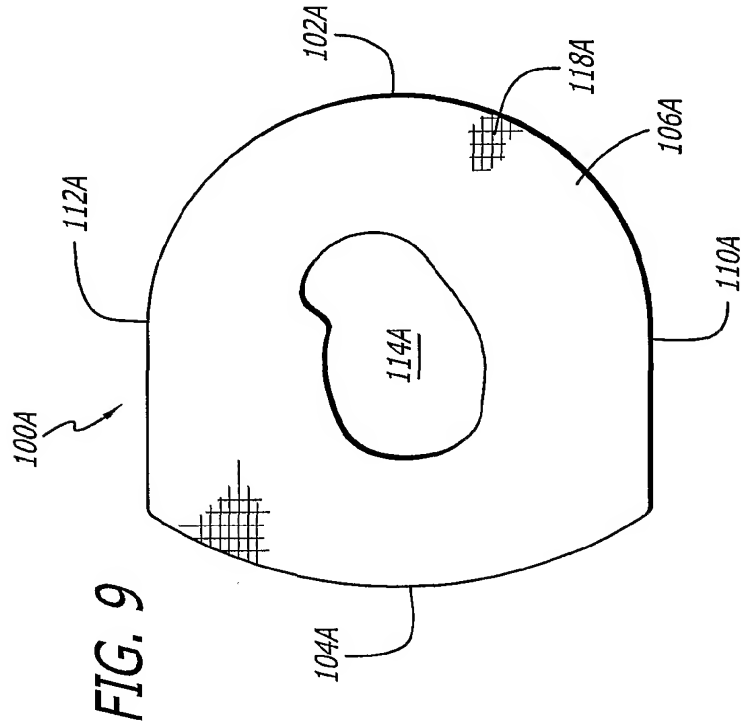
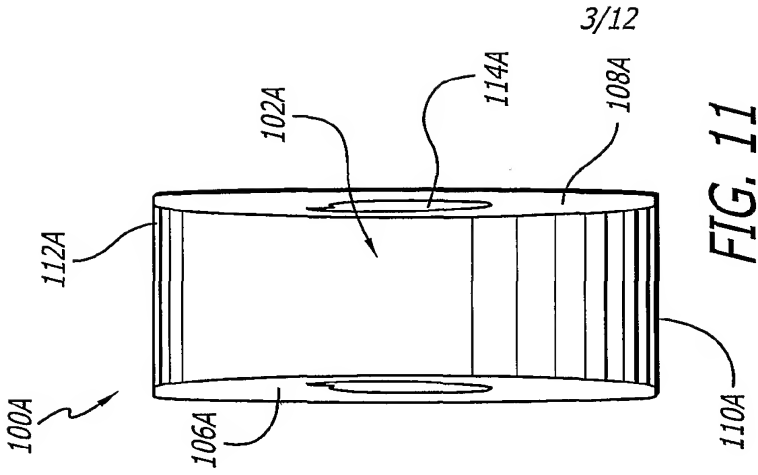


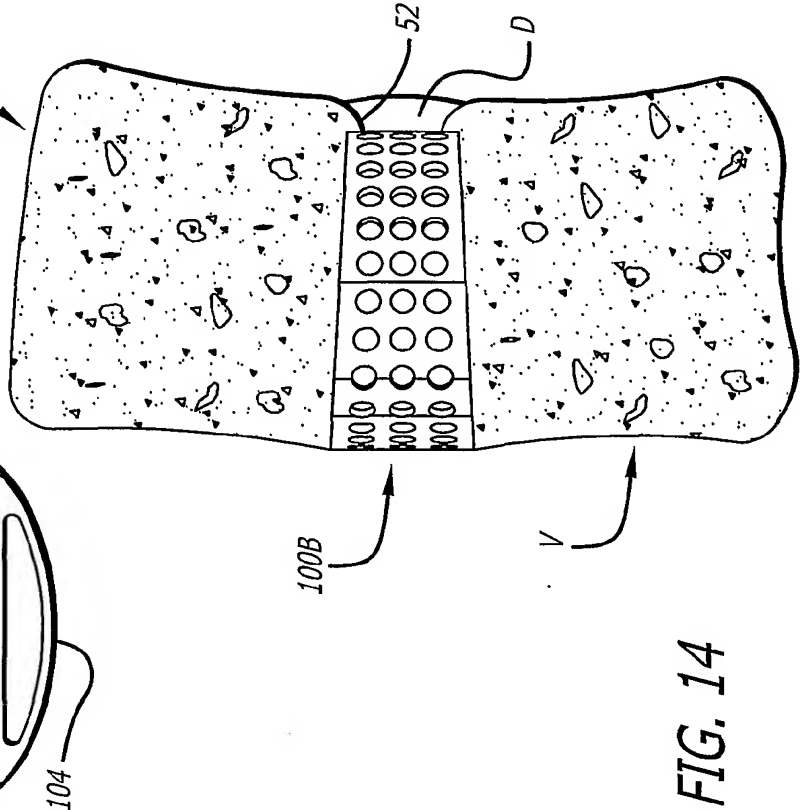
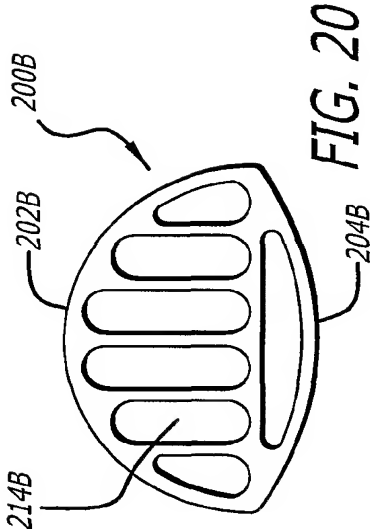
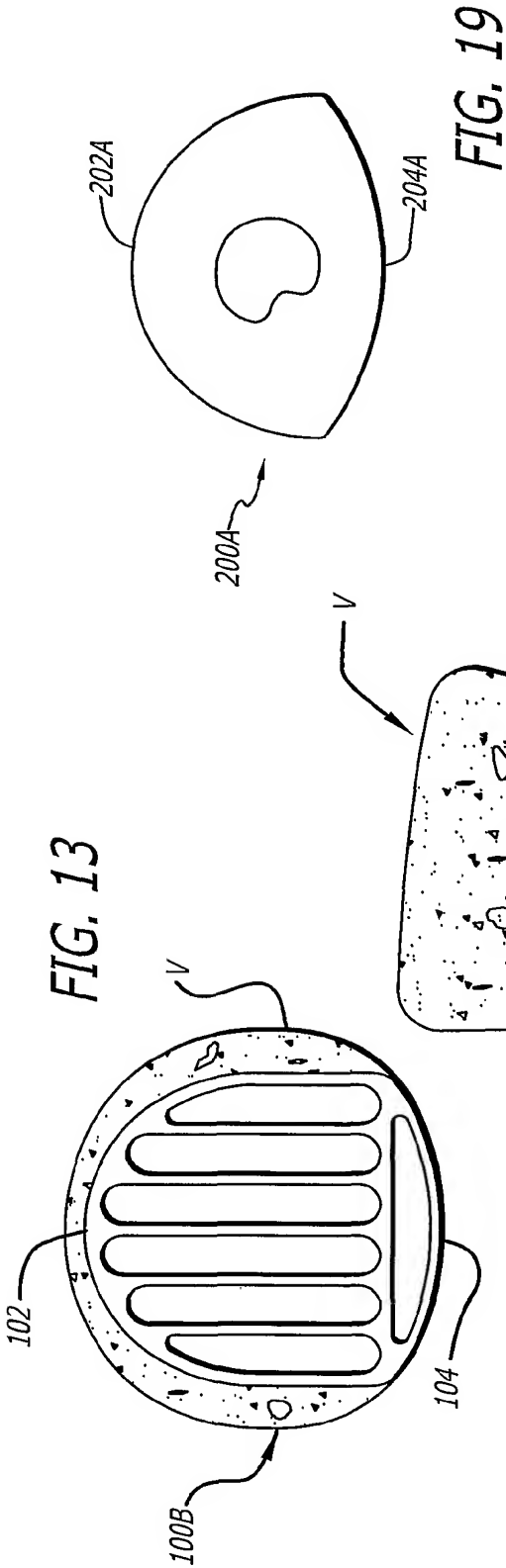
176. The implant of claim 175, wherein at least one of said opposite sides is at least in part straight along at least a portion of the length of said implant.
177. The implant of claim 175, wherein said implant has a mid-longitudinal axis along the length, at least one of said opposite sides being at least in part oriented generally parallel to the mid-longitudinal axis of said implant.
178. The implant of claim 175, wherein said opposite sides are at least in part generally parallel one another. *cl*
179. The implant of claim 166, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.
180. The implant of claim 166, wherein said implant has a maximum length less than and approximating the posterior to anterior depth of the vertebral bodies.
181. The implant of claim 166, further comprising a bone engaging surface formed on the exterior of at least said upper and lower portions for engaging the adjacent vertebral bodies, said bone engaging surface including at least one of a protrusion, a ratchet, a spike, a spline, surface roughenings, and knurling.
182. The implant of claim 166, wherein said implant includes at least two members, each member having a leading portion, a trailing portion, a top, a bottom, and at least one side, each member being adapted to be placed side by side with another of said members, said leading portion of said members forming said leading end of said implant when placed side by side.
183. The implant of claim 182, wherein said implant includes two of said members, each member being a mirror image of the other.
184. The implant of claim 182, wherein each member includes at least a portion of said at least one opening.
185. The implant of claim 166, in combination with a bone growth promoting material.
186. The implant of claim 185, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone

- matrix, mineralizing proteins, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
187. The implant of claim 166, wherein said implant is treated with a bone growth promoting substance.
  188. The implant of claim 166, wherein said implant is at least in part resorbable.
  189. The implant of claim 166, in combination with a chemical substance adapted to inhibit scar formation.
  190. The implant of claim 166, in combination with an antimicrobial material.
  191. The implant of claim 166, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.
  192. The implant of claim 166, in combination with at least one spinal fixation implant.
  193. The implant of claim 175, further comprising a curved transition between at least one of said opposite sides and said trailing end, said curved transition forming at least part of an arc of a circle.
  194. The implant of claim 16630, wherein said trailing end is adapted to receive at least one bone screw adapted to engage at least one vertebral body when inserted through said implant.
  195. The implant of claim 194, further comprising a lock for locking at least one bone screw to said implant.









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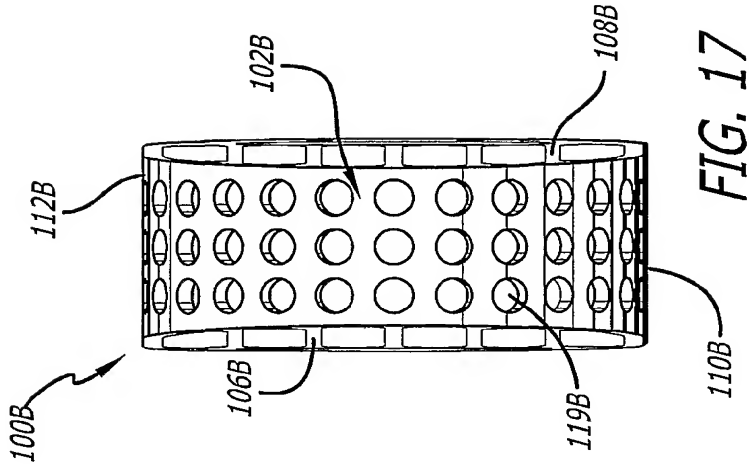


FIG. 17

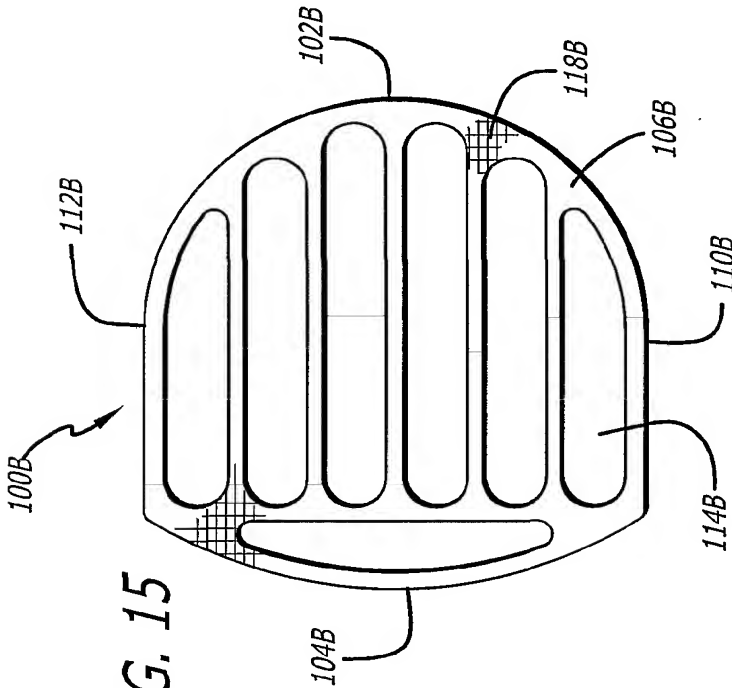


FIG. 15

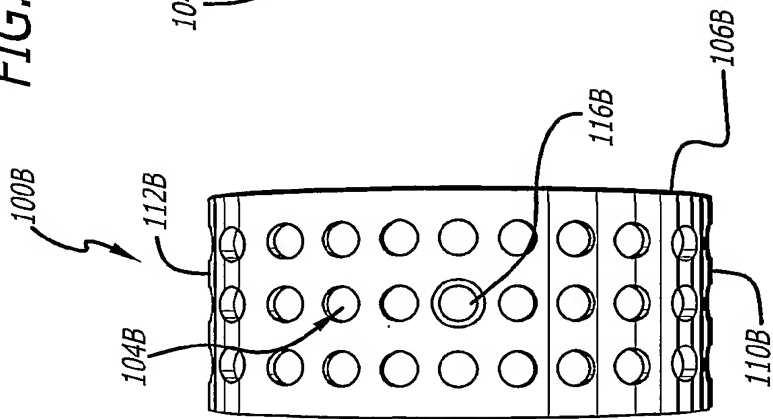


FIG. 18

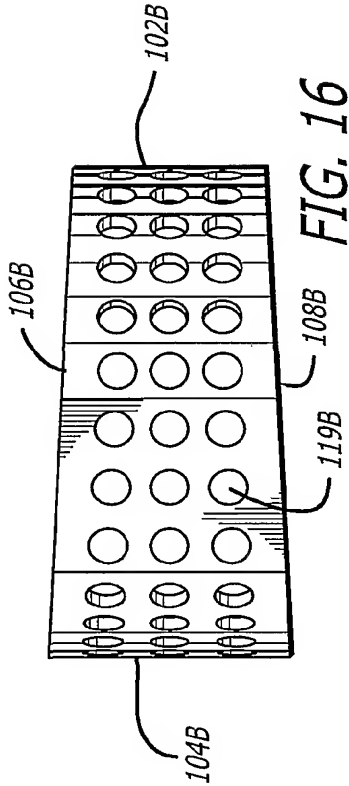
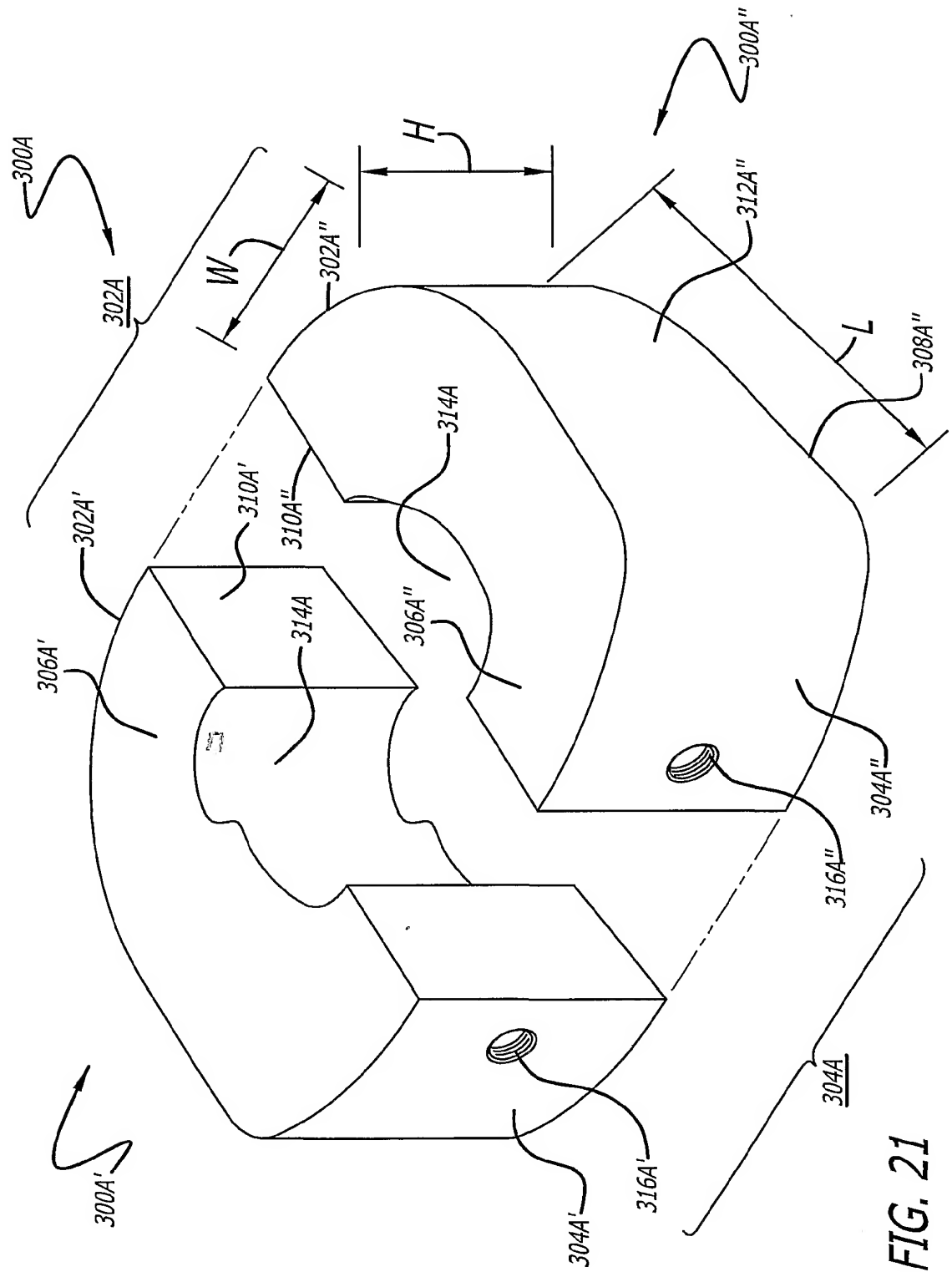
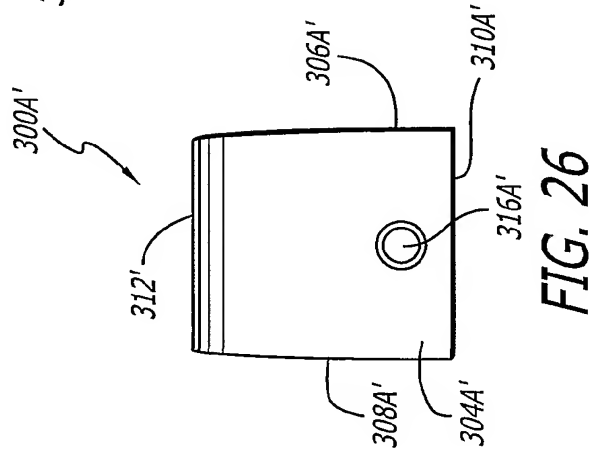
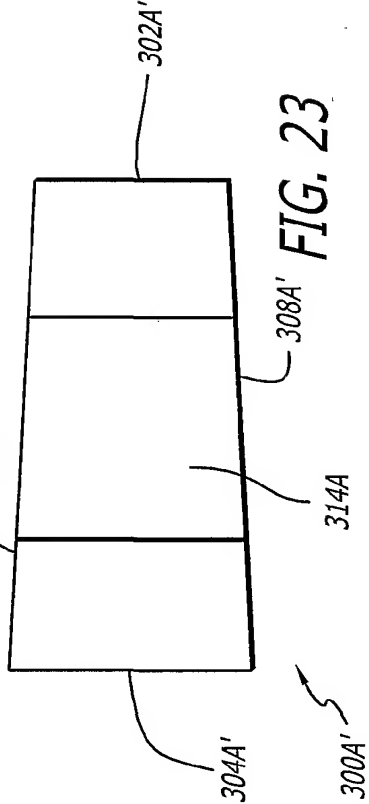
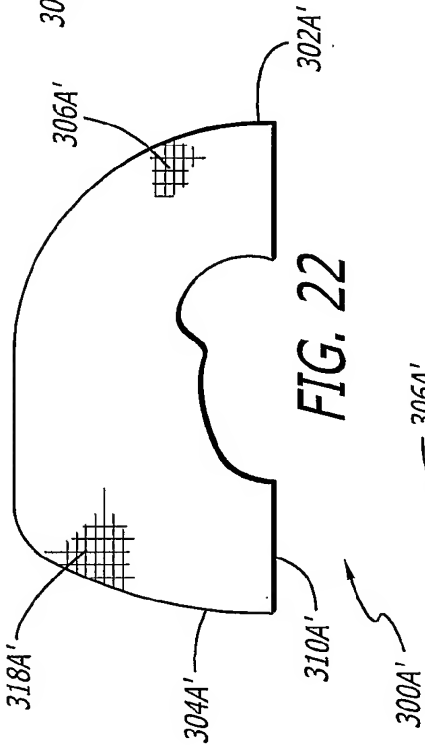
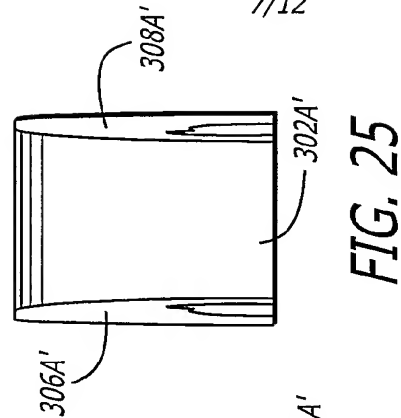
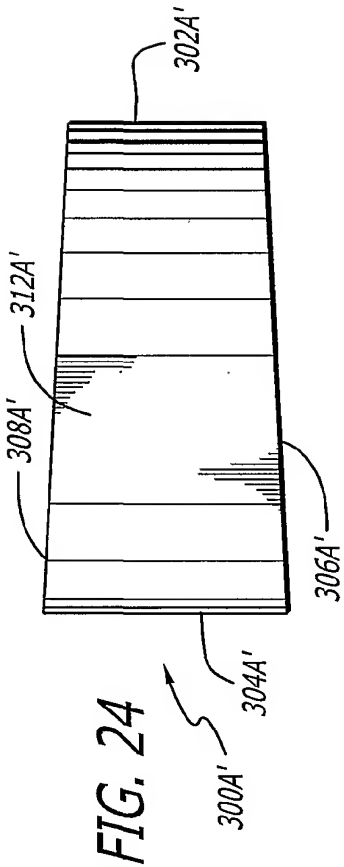
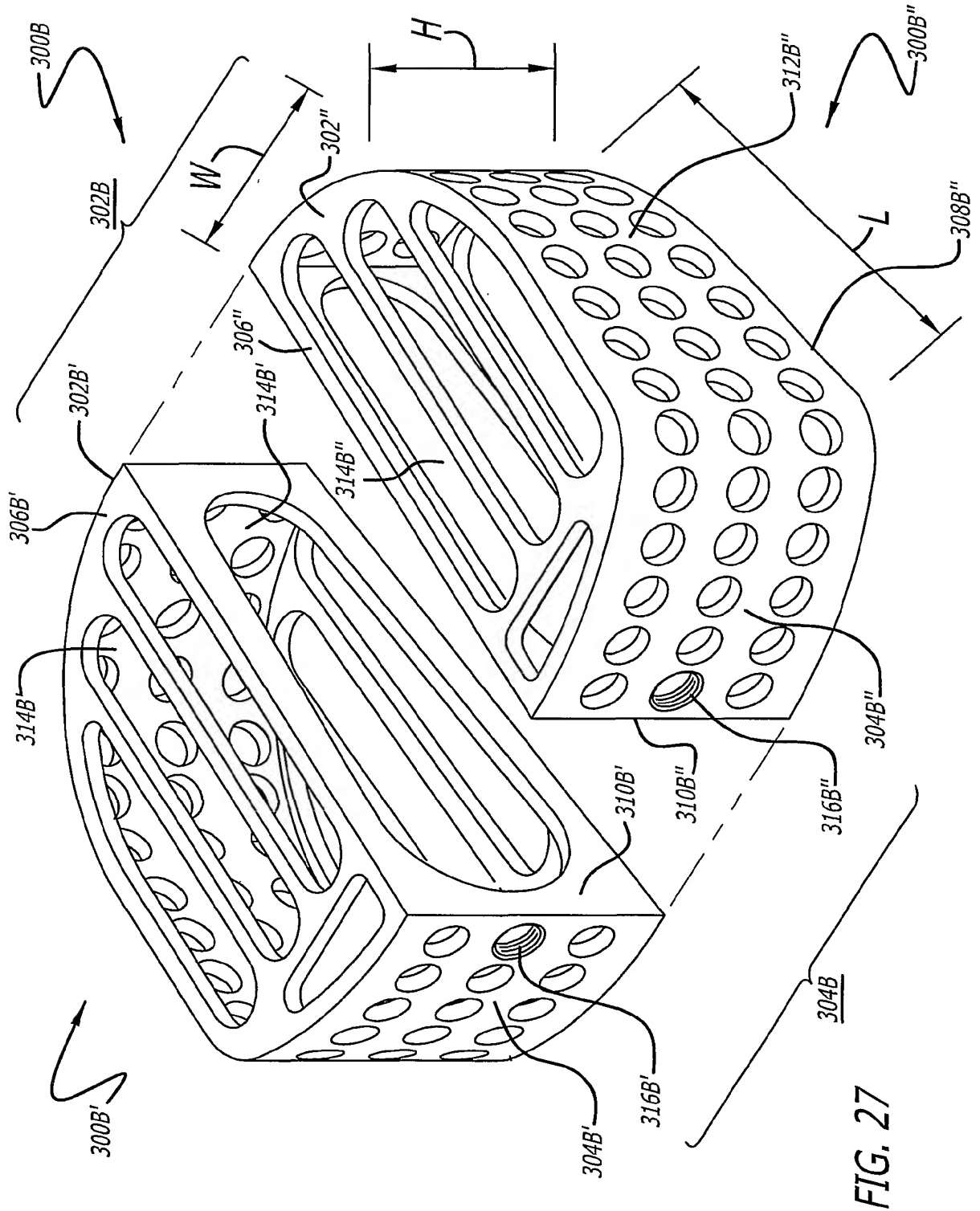


FIG. 16









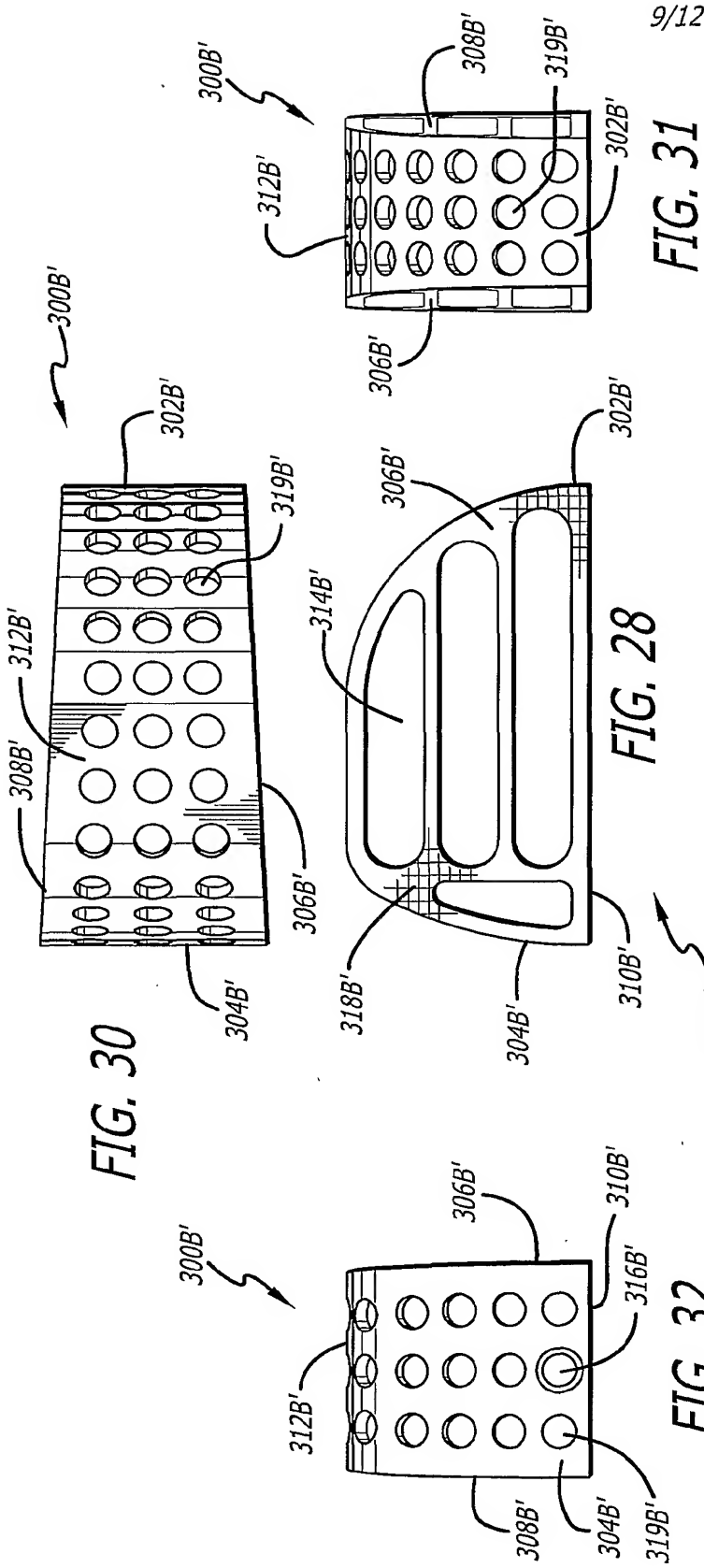


FIG. 33

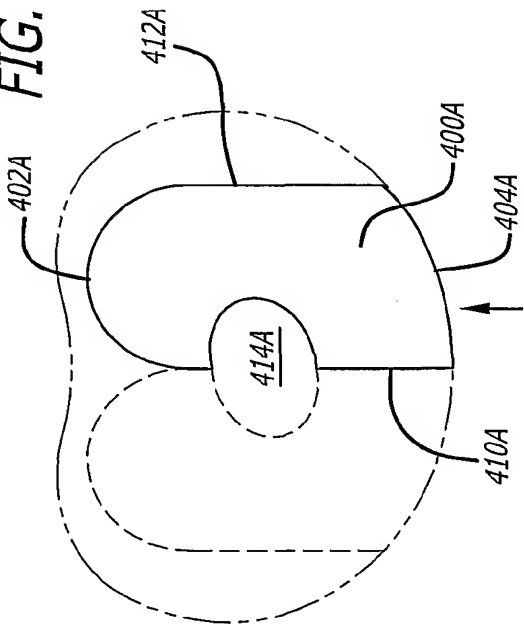


FIG. 34

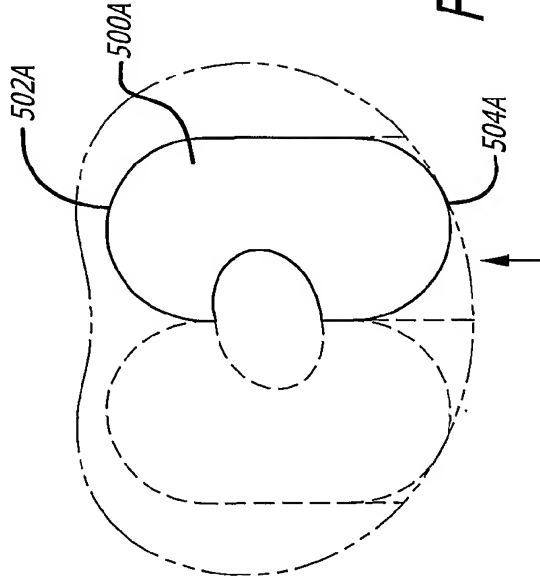
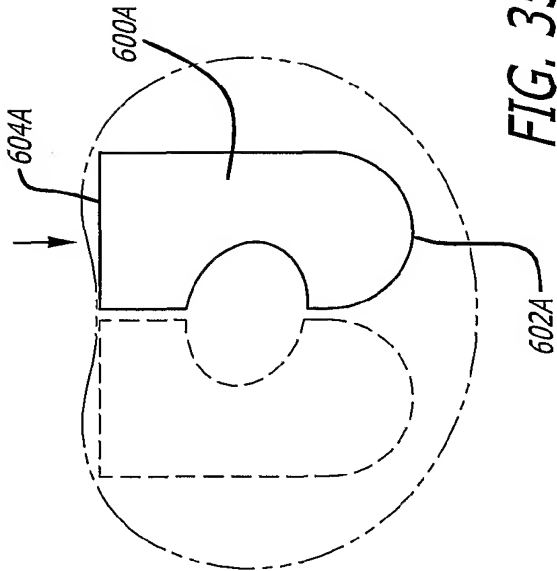
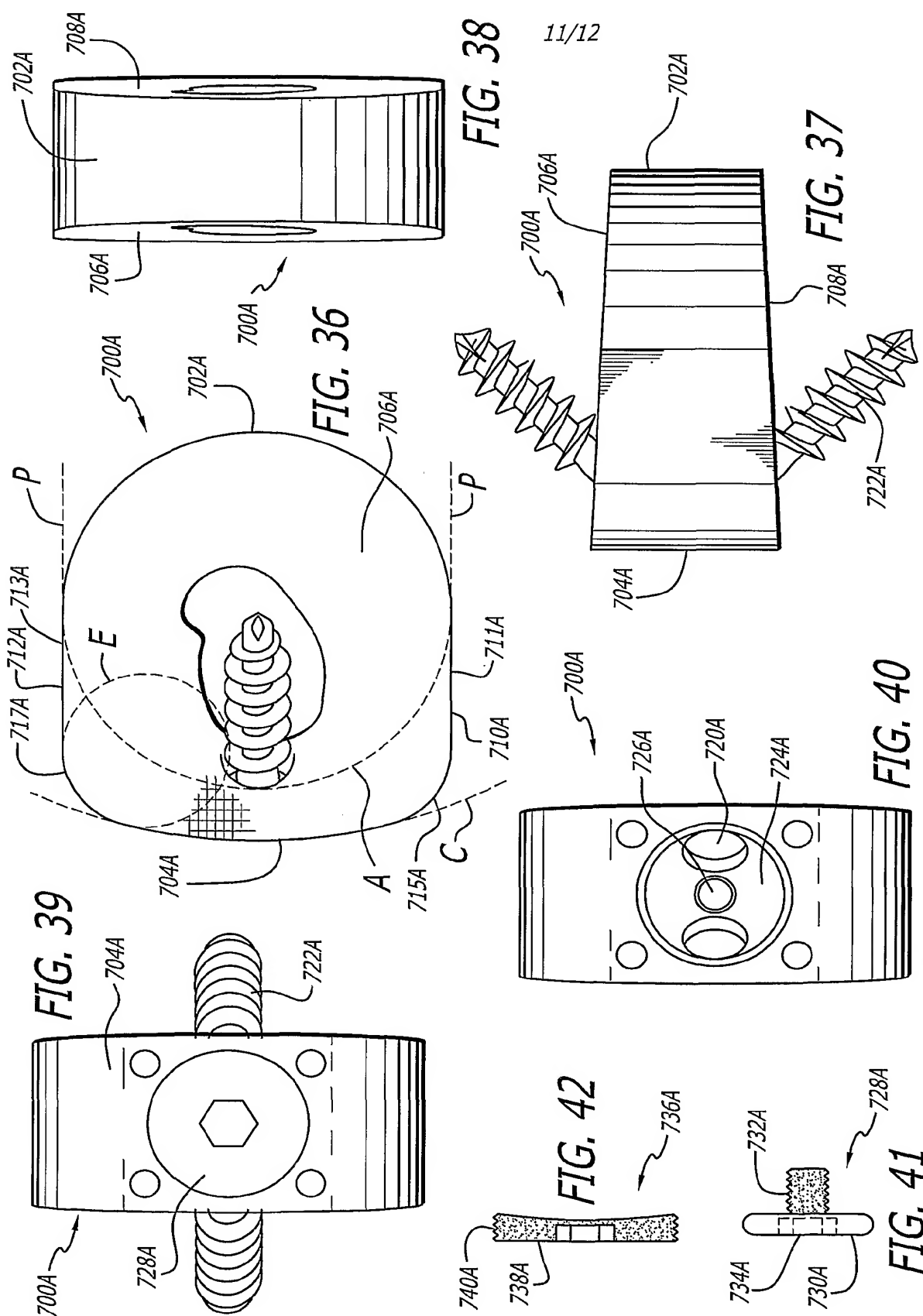
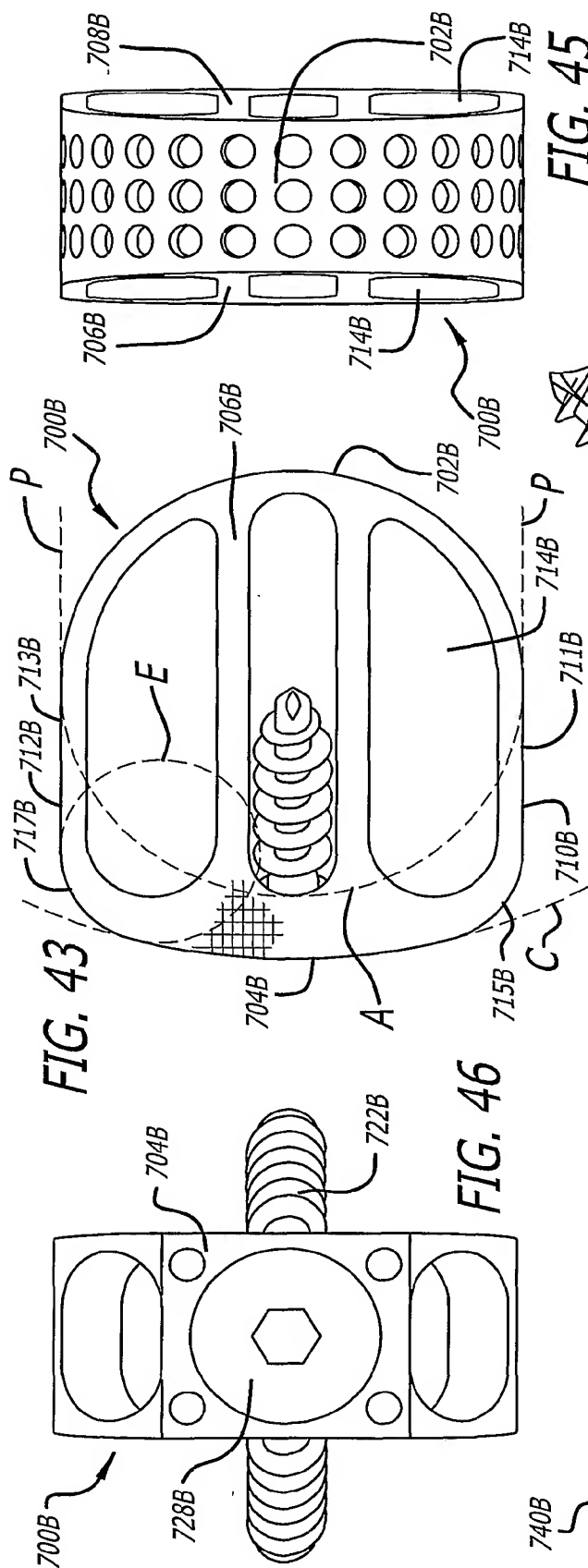


FIG. 35

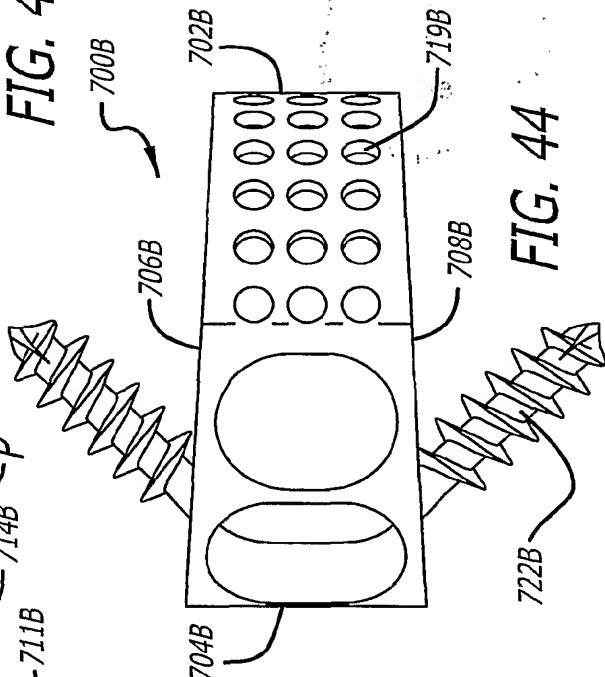




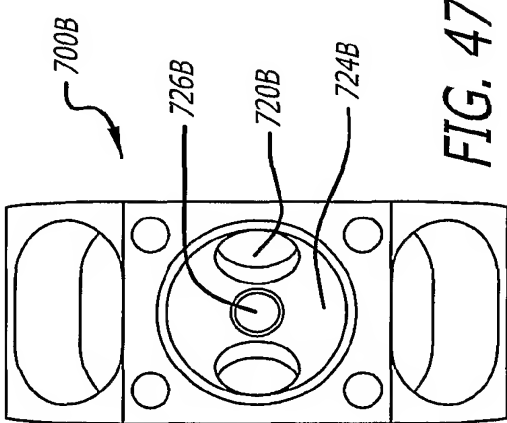


**FIG. 45**

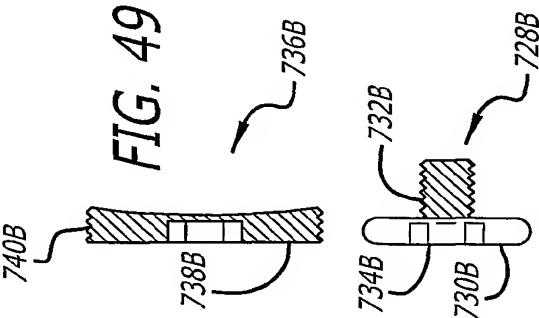
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**FIG. 47**



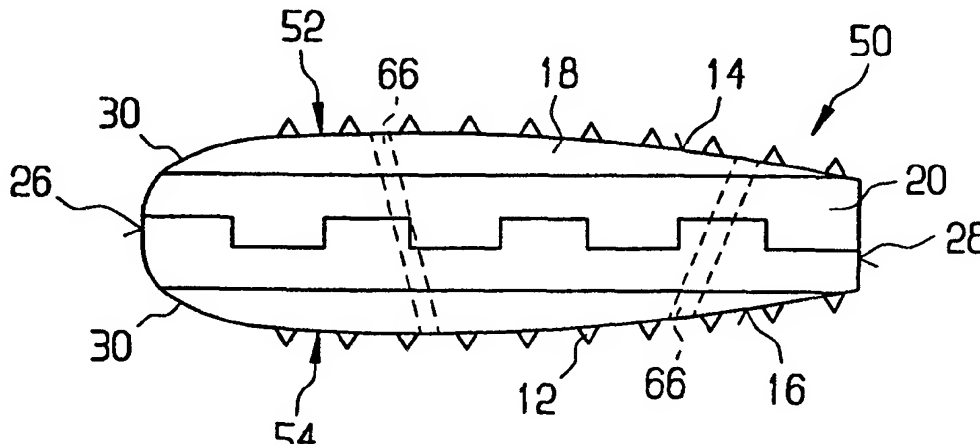
**FIG. 49**



**FIG. 48**



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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|--|-----------|---|
| <b>(51) International Patent Classification <sup>7</sup> :</b><br><b>A61F 2/44</b>   | <b>A1</b> | <b>(11) International Publication Number:</b> <b>WO 00/07527</b><br><b>(43) International Publication Date:</b> 17 February 2000 (17.02.00)   |
| <b>(21) International Application Number:</b> PCT/EP99/05541<br><b>(22) International Filing Date:</b> 30 July 1999 (30.07.99)<br><br><b>(30) Priority Data:</b><br>60/095,209      3 August 1998 (03.08.98)      US<br>PCT/EP99/05008      15 July 1999 (15.07.99)      EP<br><br><b>(71) Applicant (for all designated States except CA):</b> SYNTHES AG<br>CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH),<br><br><b>(71) Applicant (for CA only):</b> SYNTHES (U.S.A.) [US/US]; 1690<br>Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).<br><br><b>(72) Inventors:</b> PAUL, David; 1513 Valley Road, Drexel Hill,<br>PA 19025 (US). EMCH, Hansjuerg; 1527 Spruce Street,<br>Philadelphia, PA 19102 (US). SCHENK, Beat; 59 Cobble-<br>stone Drive, Paoli, PA 19301 (US).<br><br><b>(74) Agent:</b> LUSUARDI, Werther; Dr. Lusuardi AG,<br>Kreuzbühlstrasse 8, CH-8008 Zürich (CH). |           | <b>(81) Designated States:</b> CA, European patent (AT, BE, CH, CY,<br>DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT,<br>SE).<br><br><b>Published</b><br><i>With international search report.</i><br><i>Before the expiration of the time limit for amending the</i><br><i>claims and to be republished in the event of the receipt of</i><br><i>amendments.</i> |
| <b>(54) Title:</b> INTERVERTEBRAL ALLOGRAFT SPACER<br><br><br><b>(57) Abstract</b><br><p>An allogenic implant (10; 40; 50; 70), particularly an allogenic intervertebral implant (10; 40; 50; 70; 80) for fusing vertebrae is disclosed. The implant (10; 40; 50; 70; 80) is a piece of allogenic bone conforming in size and shape with portions of end plates of a vertebrae. The implant (10; 40; 50; 70; 80) has a wedge-shaped profile to restore disc height and the natural curvature of the spine. The top and bottom surfaces (14; 16) of the implant have a plurality of teeth (12) to resist expulsion and provide initial stability. The implant (10; 40; 50; 70; 80) according to the present invention provides initial stability needed for fusion without stress shielding.</p>              |           |   |

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| BR | Brazil                   | IL | Israel                                   | MW | Malawi                                       | UG | Uganda                   |
| BY | Belarus                  | IS | Iceland                                  | MX | Mexico                                       | US | United States of America |
| CA | Canada                   | IT | Italy                                    | NE | Niger  | UZ | Uzbekistan               |
| CF | Central African Republic | JP | Japan                                    | NL | Netherlands                                  | VN | Viet Nam                 |
| CG | Congo                    | KE | Kenya                                    | NO | Norway                                       | YU | Yugoslavia               |
| CH | Switzerland              | KG | Kyrgyzstan                               | NZ | New Zealand                                  | ZW | Zimbabwe                 |
| CI | Côte d'Ivoire            | KP | Democratic People's<br>Republic of Korea | PL | Poland                                       |    |                          |
| CM | Cameroon                 | KR | Republic of Korea                        | PT | Portugal                                     |    |                          |
| CN | China                    | KZ | Kazakstan                                | RO | Romania                                      |    |                          |
| CU | Cuba                     | LC | Saint Lucia                              | RU | Russian Federation                           |    |                          |
| CZ | Czech Republic           | LI | Liechtenstein                            | SD | Sudan  |    |                          |
| DE | Germany                  | LK | Sri Lanka                                | SE | Sweden                                       |    |                          |
| DK | Denmark                  | LR | Liberia                                  | SG | Singapore                                    |    |                          |
| EE | Estonia                  |    |  |    |  |    |                          |



## INTERVERTEBRAL ALLOGRAFT SPACER

The present invention is directed to an allogenic implant according to the definition of claim 1. More particularly, it refers to an allogenic intervertebral implant conforming in size and shape with end plates of vertebrae.

A number of medical conditions such as compression of spinal cord nerve roots, degenerative disc disease, and spondylolisthesis can cause severe low back pain. Intervertebral fusion is a surgical method of alleviating low back pain. In posterior lumbar interbody fusion ("PLIF"), two adjacent vertebral bodies are fused together by removing the affected disc and inserting an implant that would allow for bone to grow between the two vertebral bodies to bridge the gap left by the disc removal.

A number of different implants and implant materials have been used in PLIF with varying success. Current implants used for PLIF include threaded titanium cages and allografts. Threaded titanium cages suffer from the disadvantage of requiring drilling and tapping of the vertebral endplates for insertion. In addition, the incidence of subsidence in long term use is not known. Due to MRI incompatibility of titanium, determining fusion is problematic. Finally, restoration of lordosis, i.e., the natural curvature of the lumbar spine is very difficult when a cylindrical titanium cage is used.

Allografts are sections of bone taken from a long bone of a donor. A cross section of the bone is taken and processed using known techniques to preserve the allograft until implantation and reduce the risk of an adverse immunological response when implanted. For example, U.S. Patent No. 4,678,470 discloses a method for processing a bone grafting material which uses glutaraldehyde tanning to produce a non-antigenic, biocompatible material. Allografts have mechanical properties which are similar to the shielding that occurs with metallic implants. They are also MRI compatible so that fusion can be more accurately ascertained and promote the formation of bone, i.e., osteoconductive. Although the osteoconductive nature of the allograft provides a biological interlocking between the allograft and the vertebrae for long term mechanical strength, initial and short term mechanical strength of the interface between the allograft

and the vertebrae are lacking as evidenced by the possibility of the allograft being expelled after implantation.

Currently commercially available allografts are simply sections of bone not specifically designed for use in PLIF. As a result, the fusion of the vertebral bodies does not occur in optimal anatomical position. A surgeon may do some minimal intraoperative shaping and sizing to customize the allograft for the patient's spinal anatomy. However, significant shaping and sizing of the allograft is not possible due to the nature of the allograft. Even if extensive shaping and sizing were possible, a surgeon's ability to manually shape and size the allograft to the desired dimensions is severely limited.

Most PLIF implants, whether threaded cages or allograft, are available in different sizes and have widths that vary with the implant height. For example, the width of a cylindrical cage will be substantially equivalent with the implant height. Although larger heights may be clinically indicated, wider implants are generally not desirable since increased width requires removal of more of the facet, which can lead to decreased stability, and more retraction of nerve roots, which can lead to temporary or permanent nerve damage.

As the discussion above illustrates, there is a need for an improved implant for fusing vertebrae.

The invention solves the posed problem with an implant that shows the features of claim 1. Additional advantageous embodiments of the invention are characterized in the subclaims.

The present invention relates to an allogenic intervertebral implant for use when surgical fusion of vertebral bodies is indicated. The implant comprises a piece of allogenic bone conforming in size and shape with a portion of the end plates of the vertebrae and has a wedge-shaped profile with a plurality of teeth located on top and bottom surfaces. The top and bottom surfaces can be flat planar surfaces or curved surfaces to mimic the topography of the end plates. The implant has a channel on at least one side for receiving a surgical tool. This channel runs in the anterior direction to accommodate a

variety of surgical approaches. A threaded hole on the anterior, posterior, posterior-lateral, or lateral side can be provided for receiving a threaded arm of an insertion tool.

In another embodiment, the implant has an interior space for receiving an osteoconductive material to promote the formation of new bone.

In another embodiment, the implant is made in two halves: a top portion having a top connecting surface and a bottom portion having a bottom connecting surface. The top connecting surface mates with the bottom connecting surface when the top and bottom portions are joined. The top and bottom portions have holes that align for receiving a pin to secure the top and bottom portions together. The pin can be made of allogenic bone.

In yet another embodiment, the medial side of the implant has a scalloped edge such that when a first implant is implanted with a second implant with the medial sides facing each other, the scalloped edges define a cylindrical space.

The present invention also relates to a discrete spacer used in conjunction with any of the other embodiments of the implant. The spacer comprises a piece of allogenic bone conforming in size and shape with a portion of an end plates of the vertebrae and has a wedge-shaped profile with substantially smooth top and bottom surfaces. The intersecting regions between the top and bottom surfaces and at least of the lateral sides and the intersecting region between the anterior and posterior sides and the same lateral side are curved surfaces to facilitate implantation of the spacer. Thus, the spacer can be implanted through an opening on one side of the spinal canal and moved with a surgical instrument to the contralateral side.

The invention and additional embodiments of the invention are explained in even more detail with reference to the partially schematic illustration of the embodiments.

In the drawings:

FIG. 1 is a top view of a first embodiment of the implant according to the present invention;

FIG. 2 is a side view of the implant of FIG. 1;

FIG. 3 is a back view of the implant of FIG. 1;

FIG. 4 is a top view of a second embodiment of the implant;

FIG. 5 is a side view of the implant of FIG. 4;

FIG. 6 is a top view of a third embodiment of the implant;

FIG. 7 is a side view of the implant of FIG. 6;

FIG. 8A is a top view of a top connecting surface of a top portion of the implant of FIG. 6;

FIG. 8B is a top view of a bottom connecting surface of a bottom portion of the implant of FIG. 6;

FIG. 9 is a perspective view of a fourth embodiment of the implant;

FIG. 10A is a side view of one embodiment of the teeth on the implant;

FIG. 10B is a side view of a second embodiment of the teeth of the implant,

Fig. 11 is a side view of an embodiment of the implant similar to the embodiment of Fig. 6 – 8;

Fig. 12 is a top view of a vertebral bone characteristic of those of the cervical, thoracic, or lumbar spine;

Fig. 13 is a side view of sequentially aligned vertebral bones, such as are found in the cervical, thoracic, or lumbar spine;

Fig. 14 is a posterior view of a sequence of vertebrae; and

Fig. 15 is an end view of another embodiment of the implant.

FIG. 1 shows a top view of a first embodiment of intervertebral allograft spacer or implant 10 according to the present invention. Implant 10 conforms in size and shape with a portion of end plates of the vertebrae between which implant 10 is to be implanted. Because implant 10 is an allograft, implant 10 promotes the formation of new bone to fuse the two vertebral bodies together. Although implant 10 will probably be predominantly used in the lumbar region of the spine, implant 10 can be configured for implantation in any region of the spine. Implant 10 has a plurality of teeth 12 on superior and inferior surfaces 14, 16 which provide a mechanical interlock between implant 10 and the end plates. Teeth 12 provide the mechanical interlock by penetrating the end plates. The initial mechanical stability afforded by teeth 12 minimizes the risk of post-operative expulsion of implant 10. Teeth 12 can be pyramid-shaped (FIG. 10A). Preferably, the angle formed from the tip to the base is approximately 60°. Alternatively, teeth 12 have a saw tooth shape with the saw tooth running in the anterior-posterior direction (FIG. 10B).

As shown in FIG. 2 and FIG. 3, a first lateral side 18 has a channel 20 and a second lateral side 22 also has a channel 20. Channels 20 are sized to receive a surgical instrument such as an inserter for implantation of implant 10. If the inserter has a threaded arm, implant 10 can be provided with a threaded hole 24. In FIG. 2, channel 20 is shown extended only partially along first lateral side 18. Channel 20 can extend along the entire length of first lateral side 18 as shown in the embodiment of FIG. 5. In FIG. 3, channels 20 are shown on both first and second lateral sides 18, 22. It should be noted that implant 10 can also have no channels or channels on one lateral side only as shown in the embodiment of FIG. 9.

The dimensions of implant 10 can be varied to accommodate a patient's anatomy. Typically, implant 10 would have a width between 6-15 mm (in the medial-lateral direction), a length between 15-30 mm (in the anterior-posterior direction), and a height between 4-30 mm (maximum height in the superior-inferior direction). The size of implant 10 allows implant 10 to be implanted using conventional open surgical

procedures or minimally invasive procedures, such as laparoscopic surgery. Additionally, because the width is kept to a restricted size range and does not necessarily increase with implant height, taller implants can be used without requiring wider implants. Thus, facet removal and retraction of nerve roots can remain minimal.

In order to restore the natural curvature of the spine after the affected disc has been removed, implant 10 has a wedge-shaped profile. As shown in FIG. 2, this wedge shape results from a gradual decrease in height from an anterior side 26 to a posterior side 28. In anatomical terms, the natural curvature of the lumbar spine is referred to as lordosis. When implant 10 is to be used in the lumbar region, the angle formed by the wedge should be approximately between  $4.2^{\circ}$  and  $15^{\circ}$  so that the wedge shape is a lordotic shape which mimics the anatomy of the lumbar spine.

In order to facilitate insertion of implant 10, anterior side 26 transitions to superior and inferior surfaces 14, 16 with rounded edges 30. Rounded edges 30 enable implant 10 to slide between the endplates while minimizing the necessary distraction of the endplates.

Although implant 10 is typically a solid piece of allogenic bone, implant 10 can be provided with a hollow interior to form an interior space. This interior space can be filled with bone chips or any other osteoconductive material to further promote the formation of new bone.

FIG. 4 shows a top view of a second embodiment of an implant 40 according to the present invention. In general, most of the structure of implant 40 is like or comparable to the structure of implant 10. Accordingly, discussion of the like components is not believed necessary. The superior and inferior surfaces 14, 16 of implant 10 are flat planar surfaces. As seen best in FIG. 5, superior and inferior surfaces 14, 16 of implant 40 are curved surfaces which still retain the wedge-shaped profile. The curved surfaces of superior and inferior surfaces 14, 16 of implant 40 are a mirror-image of the topography of the vertebral end plates. Thus, the curved surfaces conform to the contours of the end plates.

FIG. 6 shows a top view of a third embodiment of an implant 50 according to the present invention. In general, most of the structure of implant 50 is like or comparable to the structure of implants 10, 40. Accordingly, discussion of the like components is not believed necessary. As best seen in FIG. 7, implant 50 comprises a top portion 52 joined to a bottom portion 54. As it may be difficult to obtain a single section of allogenic bone from which implant 50 is to be made, fabricating implant 50 in two pieces, i.e. top and bottom portions 52, 54, allows smaller sections of allogenic bone to be used. A top connecting surface 56 and a bottom connecting surface 58 define the interface between top and bottom portions 52, 54. As shown in FIGS. 8A and 8B, top and bottom surfaces 56, 58 have ridges 60 that mate with grooves 62 to interlock top and bottom portions 52, 54. Preferably, ridges 60 and grooves 62 are formed by milling top and bottom surfaces 56, 58 in a first direction and then milling a second time with top and bottom surfaces 56, 58 oriented 90° with respect to the first direction.

A pin 64 passing through aligned holes 66 in top and bottom portions 52, 54 serves to retain top and bottom portions 52, 54 together. Although pin 64 can be made of any biocompatible material, pin 64 is preferably made of allogenic bone. The number and orientation of pins 64 can be varied.

Fig. 11 shows an embodiment of an implant 80 which, like implant 50, is made in multiple pieces. In general, most of the structure of implant 80 is like or comparable to the structure of implants 10, 40, 50. Accordingly, discussion of the like components is not believed necessary. Implant 80 has a top portion 82, a middle portion 84, and a bottom portion 86. As was the case for implant 80, the surfaces between the portions are mating surfaces with interlocking surface features, such as ridges and grooves. One or more pins preferably hold top, middle, and bottom portions 82, 84, 86 together.

FIG. 9 shows a perspective view of a fourth embodiment of a first implant 70 according to the present invention. A second implant 70', which is substantially similar to first implant 70, is also shown. In general, most of the structure of first and second implants 70, 70' is like or comparable to the structure of implants 10, 40, 50. Accordingly, discussion of the like components is not believed necessary. First lateral sides 18 of first and second implants 70, 70' are scalloped to have a C-shape. When first and second implants 70, 70' are placed side by side with the first lateral sides 18 facing

each other, a cylindrical space 72 is formed. When first and second implants 70, 70' are implanted together, cylindrical space 72 can be filled with osteoconductive material to help promote the formation of new bone. First and second implants 70, 70' can be provided with locking pins 74 which engage apertures 76 to maintain the spatial relationship between first and second implants 70, 70'.

The use of the implant according to the present invention will now be described with reference to Fig. 12 – 14 and using posterior lumbar interbody fusion as an example. As the implant according to the present invention conforms in size and shape to a portion of end plates 100, preoperative planning is recommended for proper sizing. Determine the appropriate implant height by measuring adjacent intervertebral discs 102 on a lateral radiograph. The implant must be seated firmly with a tight fit between end plates 100 when the segment is fully distracted. The tallest possible implant should be used to maximize segmental stability. Due to variability in degrees of magnification from radiographs, the measurements are only an estimate.

With the patient in a prone position on a lumbar frame, radiographic equipment can assist in confirming the precise intraoperative position of the implant. The surgeon incises and dissects the skin from a midline laterally and locates spinous process 104, lamina 106, dura 108, and nerve roots of the appropriate level(s). As much as possible facets 110 should be preserved to provide stability to the intervertebral segment. The surgeon performs a laminotomy to the medial aspect of facet 110 and reflects dura 108 to expose an approximately 13 mm window to the disc space. Disc 102 is removed through the window until only anterior 112 and lateral 114 annulus remain. The superficial layers of the entire cartilaginous end plates 100 are also removed to expose bleeding bone. Excessive removal of the subchondral bone may weaken the anterior column. Furthermore, if the entire end plate is removed, this may result in subsidence and a loss of segmental stability.

Distraction can be done with either a surgical distractor or a trial spacer implant. In the first method, the distractor blades should be completely inserted into the disc space so that the ridges at the end of the blades rest on vertebral body 116. Fluoroscopy can assist in confirming that the distractor blades are parallel to end plates 100. Correct placement will angle the handles of the distractor cranially, particularly at L5-S1. The



handle of the distractor is squeezed to distract the innerspace. The distraction is secured by tightening the speed nut on the handle.

Using the preoperatively determined size, a trial spacer is inserted in the contralateral disc space with gentle impaction. Fluoroscopy and tactile judgement can assist in confirming the fit of the trial spacer until a secure fit is achieved. Using either the slots or threader hole on the implant, the selected implant is inserted in the contralateral disc space. Alternatively, the channels on the implant allow distraction and insertion to occur on the same side. Regardless of the side the implant is inserted in, autogenous cancellous bone or a bone substitute should be placed in the anterior and medial aspect of the vertebral disc space prior to placement of the second implant. The distractor is removed and a second implant of the same height as the first implant is inserted into the space, using gentle impaction as before. Preferably, the implants are recessed 2 – 4 mm beyond the posterior rim of the vertebral body.

As previously noted, the implant according to the present invention can be inserted using minimally invasive procedures. In some of these procedures, only one side of the spinal cord needs to be approached. This minimizes muscle stripping, scar tissue in the canal, and nerve root retraction and handling. In clinical situations in which bilateral implant placement is required, proper implantation on the side opposite the incision can be difficult. Fig. 15 shows a beveled spacer 120 that facilitates placement on the side contralateral to the incision. In general and unless otherwise described, most of the structure of beveled spacer 120 is like or comparable to the structure of implants 10, 40, 50 and 80. Accordingly, discussions of the like components is not believed necessary. First lateral side 18 transitions to superior and inferior surfaces 14, 16 with rounded edges 30. First lateral side 18 also transitions to anterior and posterior sides 26, 28 with rounded edges 30. Additionally, spacer 120 has no teeth. The lack of teeth and rounded edge 30 enable spacer 20 to slide between the end plate and across the evacuated space (from one lateral annulus to the other) to the contralateral side. As first lateral side 18 is the side that must promote movement of spacer 120, the use of rounded edges 30 on second lateral side 22 is optionally. Once spacer 120 has been placed on the side contralateral to the single incision using a surgical instrument to push spacer 120, bone graft or other osteoconductive material is packed in the disc

space. Finally, an implant (any of implant 10, 40, 50, 70 or 70' can be used) is implanted in the side proximal to the incision.

While it is apparent that the illustrative embodiments of the invention herein disclosed fulfil the objectives stated above, it will be appreciated that numerous modifications and other embodiments may be devised by those skilled in the art. Therefore, it will be understood that the appended claims are intended to cover all such modifications and embodiments which come within the scope of the present invention.

## CLAIMS

1. An implant (10;40;50;70;80) comprising a piece of allogenic bone, characterized in that the implant (10;40;50;70;80) has a plurality of planar or curved sidewalls (18;22;26;28), a top surface (14) and a bottom surface (16) in order to fit as a graft between surfaces of adjacent bones or bone fragments.
2. The implant according to claim 1, characterized in that the implant (10;40;50;70;80) has a wedge-shaped profile.
3. The implant according to claim 1 or 2, characterized in that at least one sidewall (18;22;26;28) has a channel (20) for receiving a surgical instrument.
4. The implant according to claim 3, characterized in that the channel (20) runs in an anterior-posterior direction.
5. The implant according to one of the claims 1 to 4, characterized in that the top and bottom surfaces (14;16) of the implant (10;40;50;70;80) are provided with a three-dimensional structure for interlocking with adjacent surfaces of bones or bone fragments.
6. The implant according to claim 5, characterized in that the three-dimensional structure includes a plurality of teeth (12).
7. The implant according to claim 6, characterized in that the teeth (12) have a pyramid shape.
8. The implant according to claim 6, characterized in that the teeth (12) have a saw tooth shape.
9. The implant according to one of the claims 1 to 9, characterized in that at least one sidewall (18;22;26;28) of the implant (10;40;50;70;80) has at least one hole (24) for attachment of an inserter.

10. The implant according to claim 9, characterized in that the at least one hole (24) is threaded.
11. The implant according to claim 9 or 10, characterized in that the at least one hole (24) is provided in an anterior, posterior, posterior-lateral, or lateral side.
12. The implant according to one of the claims 1 to 11, characterized in that the top and bottom surfaces (14;16) are defined by flat planar surfaces.
13. The implant according to one of the claims 1 to 12, characterized in that a region between the top and bottom surfaces (14;16) and an anterior side of the implant is a curved edge (30) to facilitate implantation of the implant.
14. The implant according to one of the claims 1 to 13, characterized in that it is an intervertebral implant (10;40;50;70;80) conforming in size and shape with a portion of end plates of vertebrae.
15. The implant according to claim 14, characterized in that the top and bottom surfaces (14;16) are defined by curved surfaces, said curved surfaces contoured to mimic surfaces of the end plates of the vertebrae.
16. The implant according to one of the claims 1 to 15, characterized in that the implant (10;40;50;70;80) has an interior space (72) for receiving an osteoconductive material.
17. The implant according to one of the claims 1 to 16, characterized in that the implant (10;40;50;70;80) further comprises a top portion (52) having a top connecting surface (56) and a bottom portion (54) having a bottom connecting surface (58), the top connecting surface (56) mating with the bottom connecting (58) surface when the top and bottom portions (52;54) are joined.
18. The implant according to claim 17, characterized in that top and bottom connecting surfaces (56;58) are provided with ridges (60) and grooves (62) that mate with each other in order to interlock the top and bottom portions (52;54).

19. The implant according to claim 17 or 18, characterized in that a pin (64) is inserted through a hole (66) in the top portion (52) and a hole (66) in the bottom portion (54) to secure the top and bottom portions (52;54) together.

20. The implant according to claim 19, characterized in that the pin (64) is made of allogenic bone.

21. The implant according to one of the claims 1 to 20, characterized in that a medial side (18) of the implant (70;70') has a scalloped edge such that when a first implant (70) is implanted with a second implant (70') with the medial sides (18) of the first and second implant (70;70') facing each other, the scalloped edges of the medial sides (18) of the first and second implants (70;70') define a cylindrical space (72).

22. The implant according to claim 21, characterized in that the first implant (70') is provided with a locking pin (74) on the medial side (18) and the second implant (70) is provided with an aperture (76) at the medial side (18) configured and dimensioned to receive the locking pin (74) to maintain the spatial relationship between the first and second implants (70;70').

23. The implant according to claim 22, characterized in that the locking pin (74) is made of allogenic bone.

24. The implant according to one of the claims 1 to 23, characterized in that the implant (10;40;50;70;80) has a width between 6 – 15 mm.

25. The implant according to one of the claims 1 to 24, characterized in that the implant (10;40;50;70;80) has a length between 15 - 30 mm.

26. The implant according to one of the claims 1 to 25, characterized in that the implant (10;40;50;70;80) has a height between 4 - 30 mm.

27. The implant according to one of the claims 1 to 26, characterized in that the implant (80) is made of a plurality of interconnecting sections (82;84;86) with mating surfaces.

28. The implant according to one of the claims 1 to 27, characterized in that it is in combination with a discrete spacer (120) comprising a piece of allogenic bone conforming in size and shape with a second portion of an end plate of a vertebra and having a wedge-shaped profile, wherein the top and bottom surfaces (14;16) of the second member are substantially smooth and regions between top and bottom surfaces (14;16) and anterior and lateral sides (26;28) of the spacer (120) have curved edges (30) to facilitate implantation of the spacer (120).

FIG 1

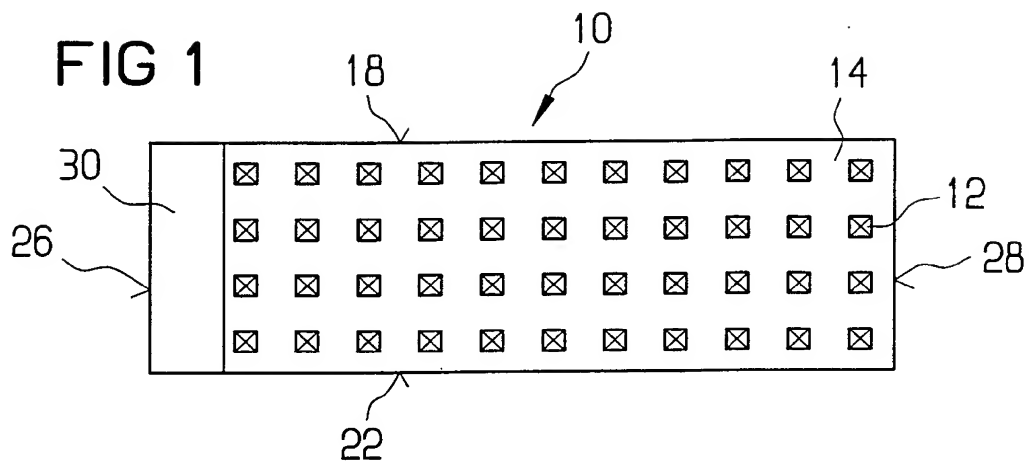


FIG 2

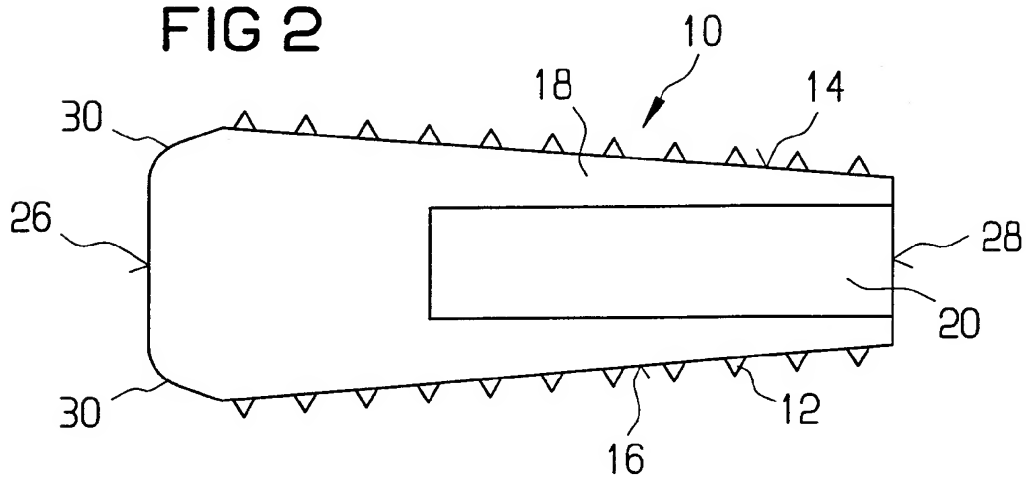


FIG 3

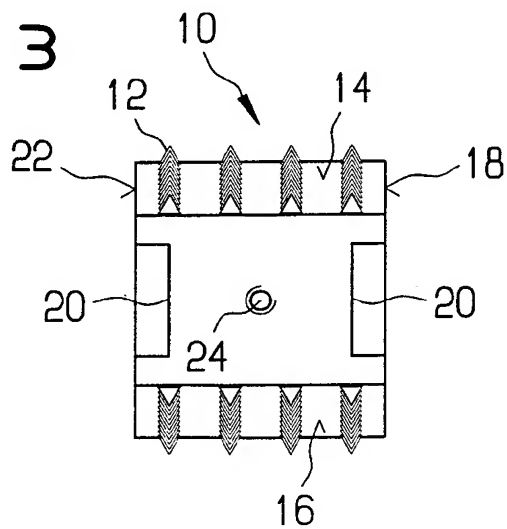


FIG 4

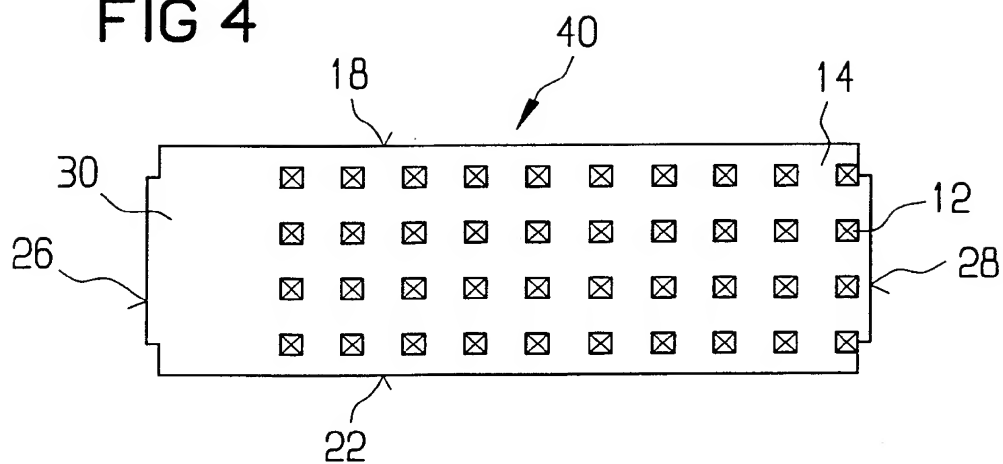


FIG 5

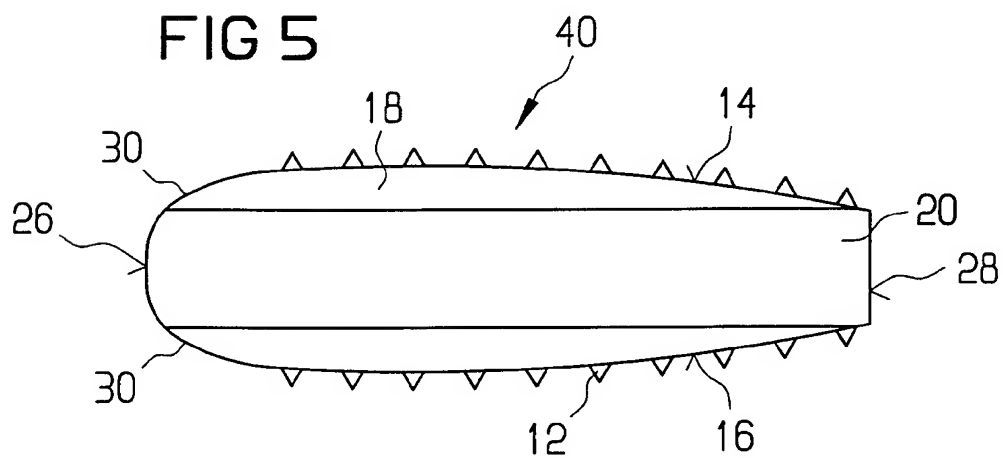




FIG 6

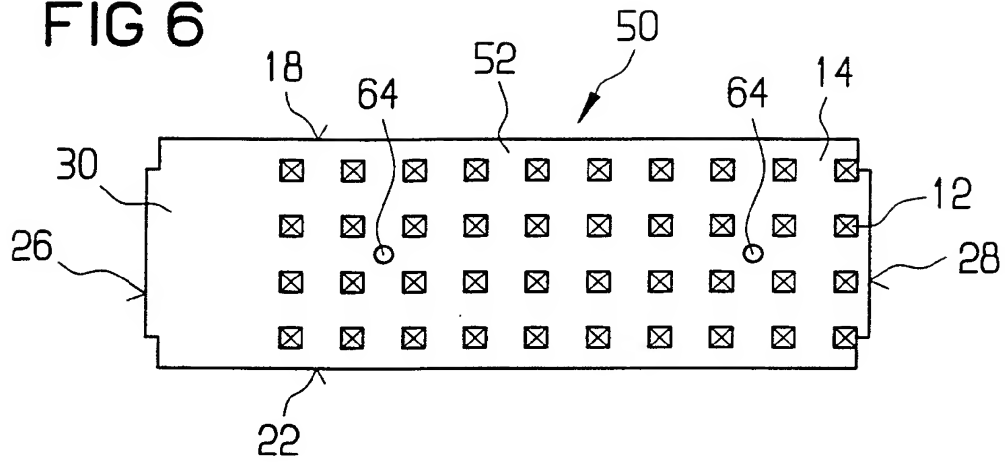


FIG 7

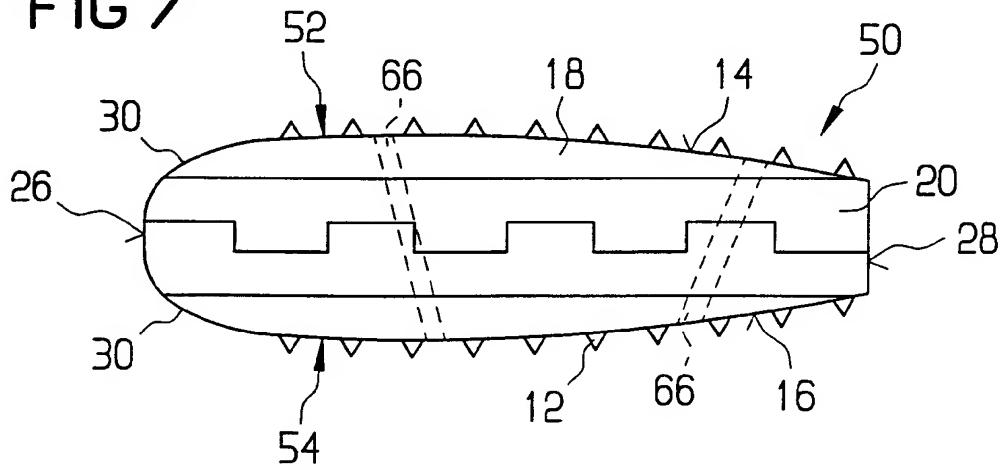


FIG 8A

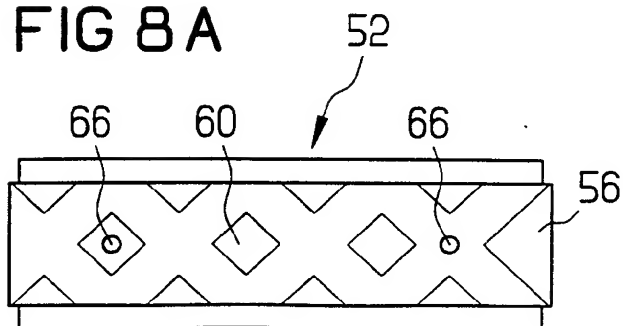


FIG 8B

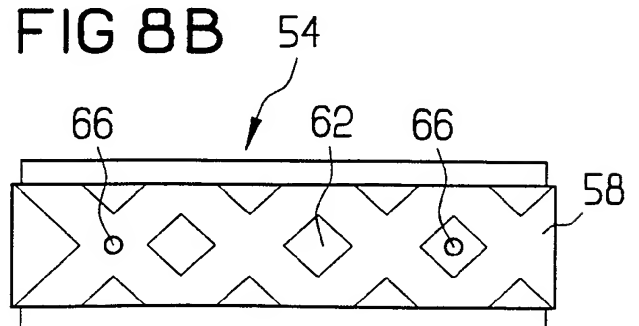


FIG 9

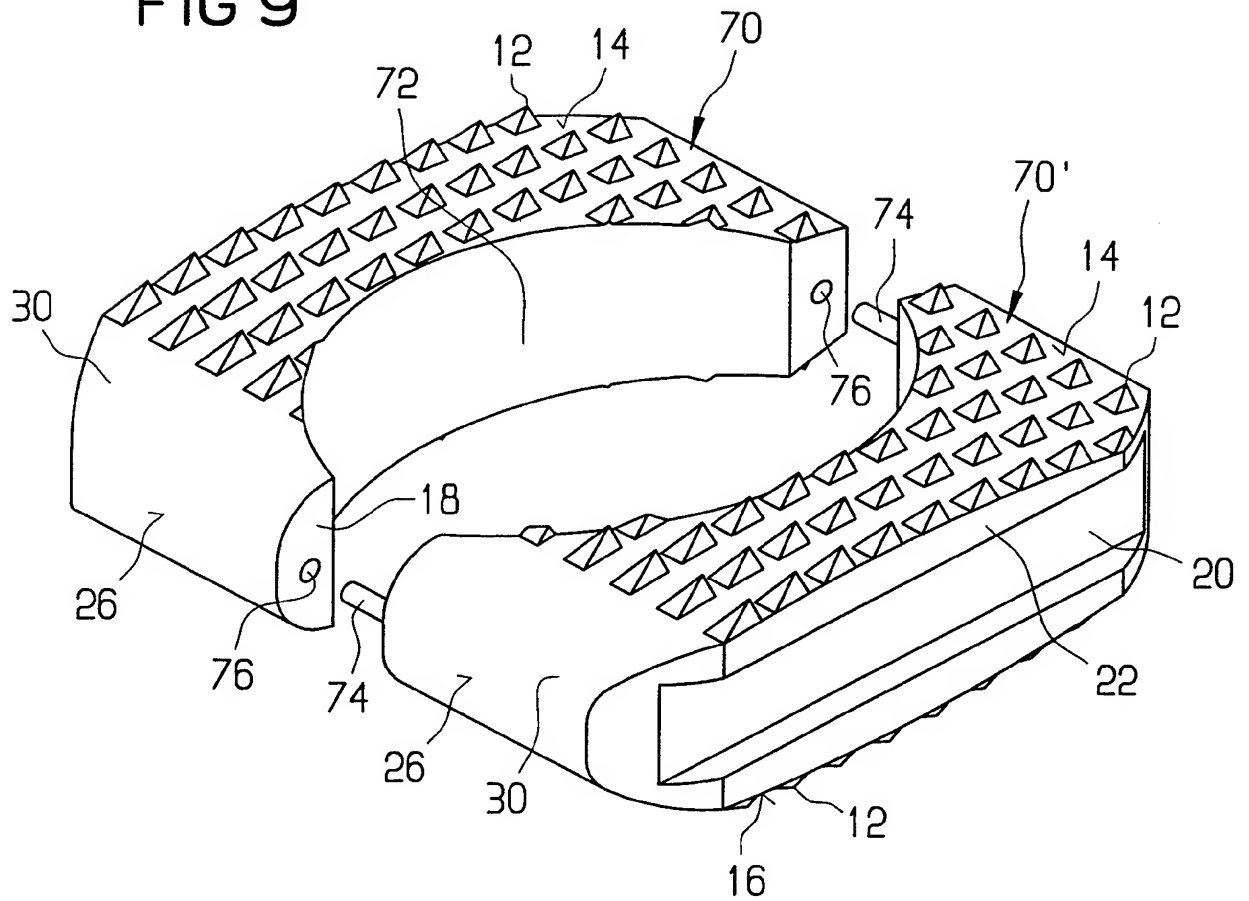


FIG 10A

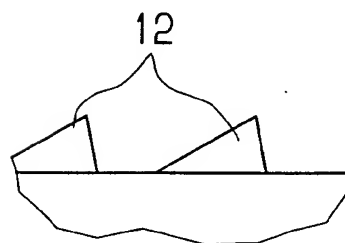


FIG 10B

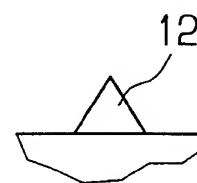


FIG 11

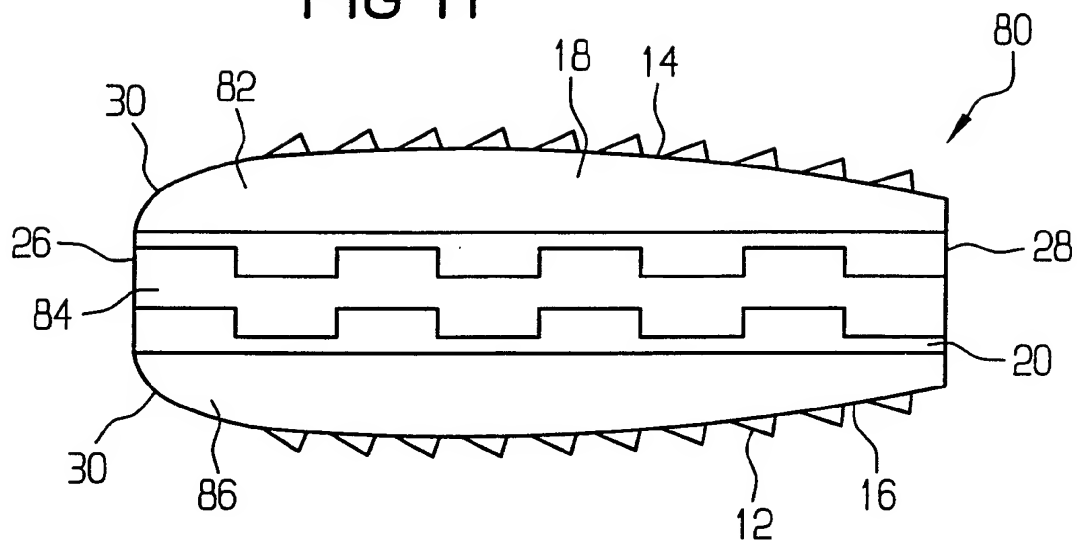
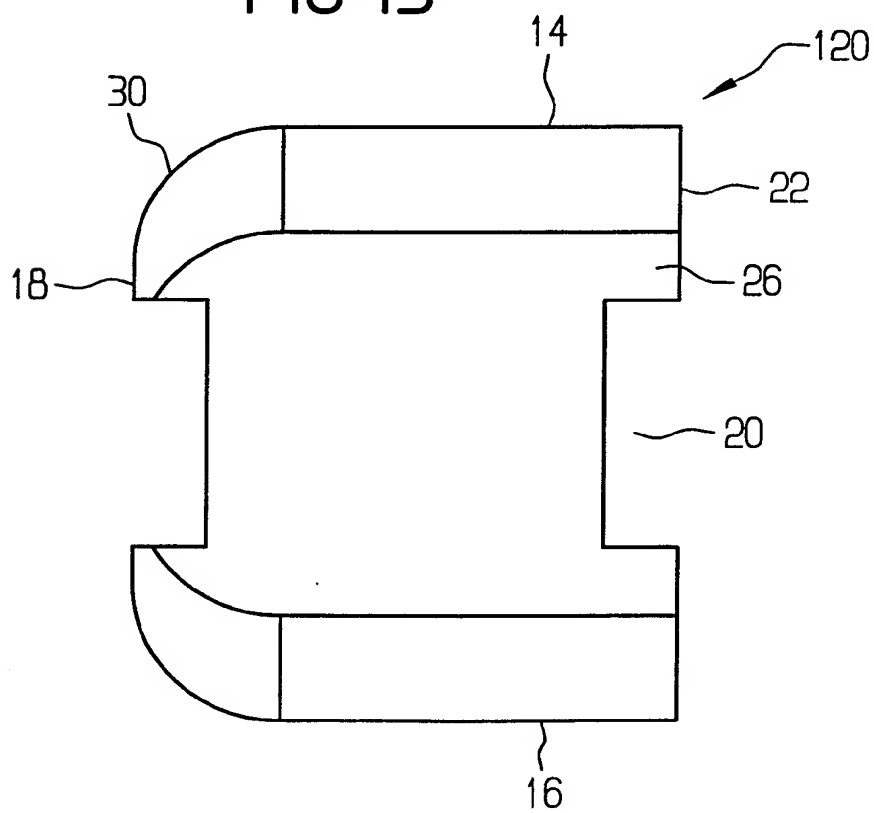


FIG 15



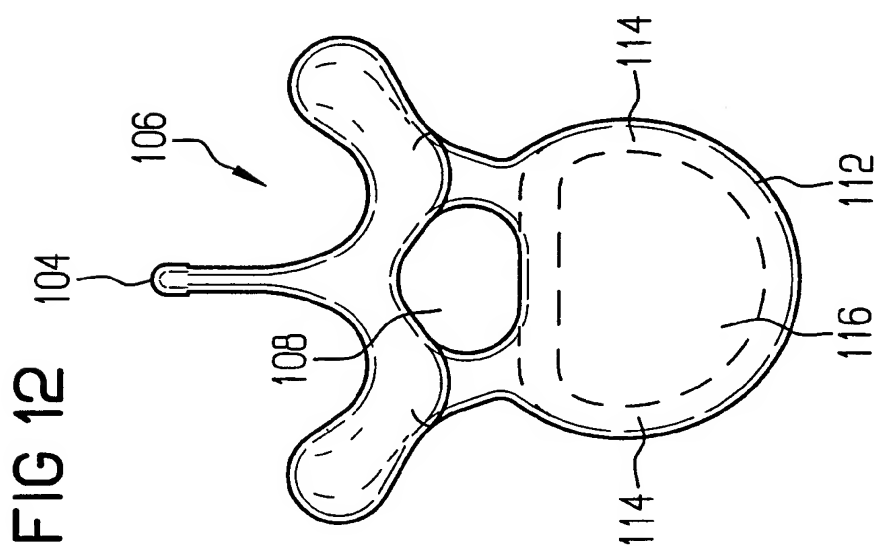
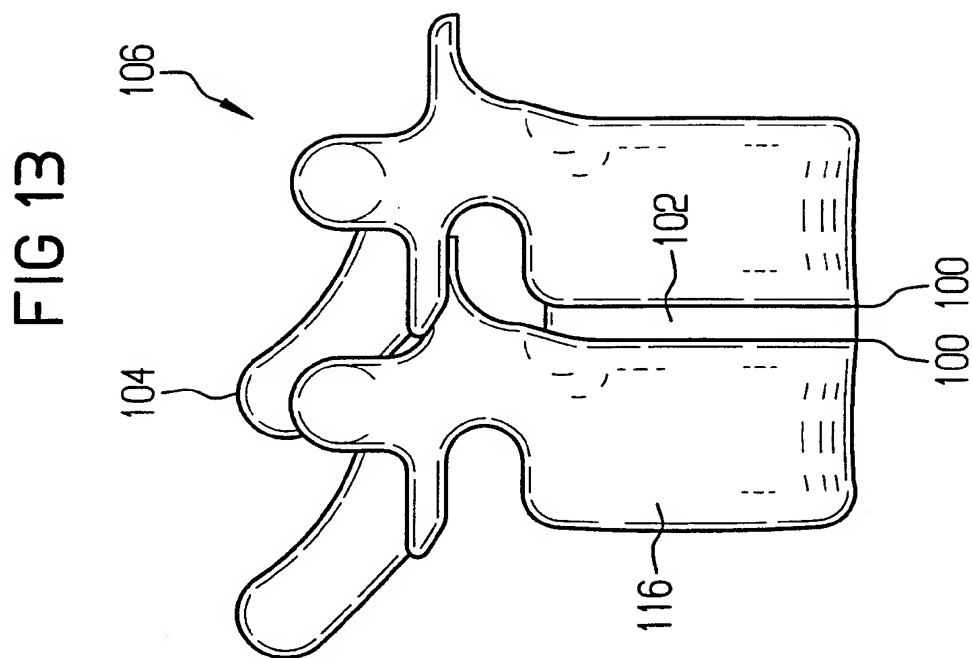
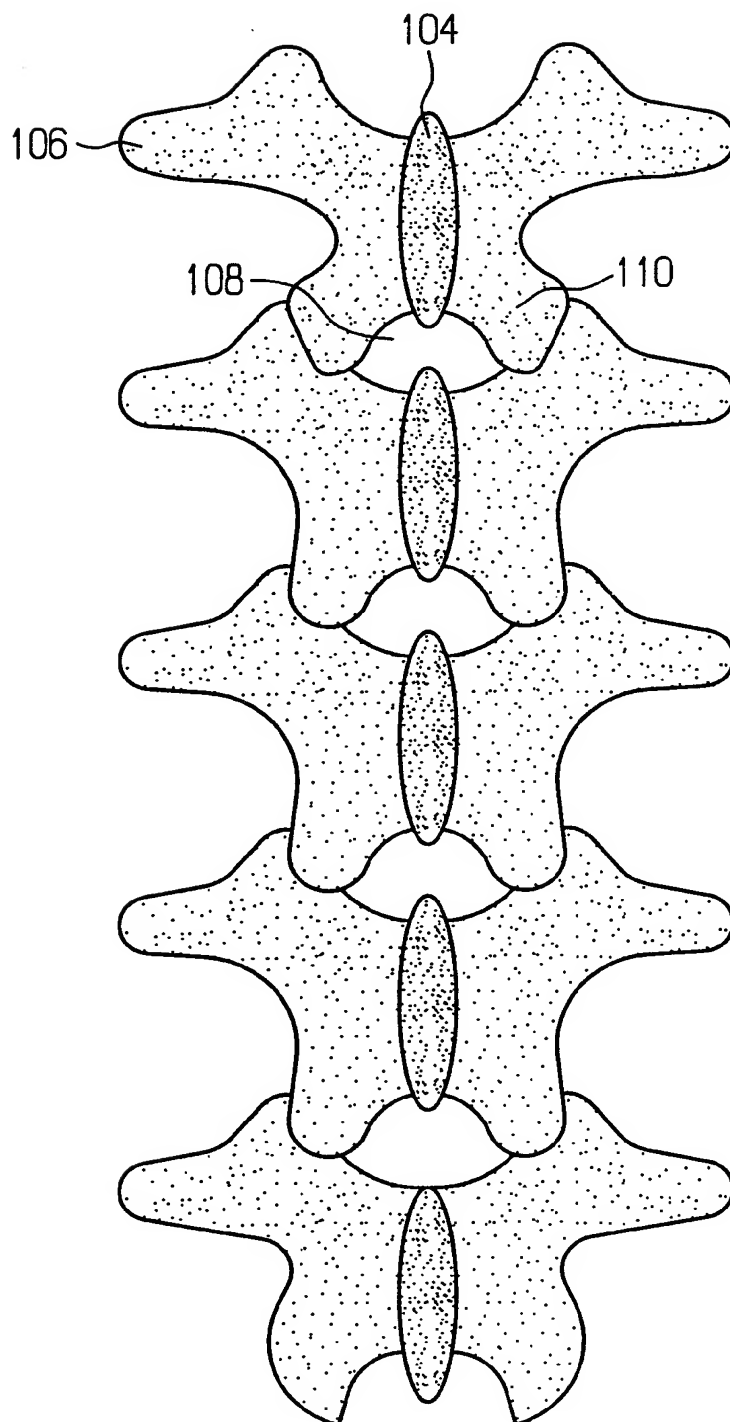


FIG 14



# INTERNATIONAL SEARCH REPORT

national Application No  
PCT/EP 99/05541

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                             | Relevant to claim No.  |
|------------|--|------------------------|
| X          | WO 95 15133 A (CALCITEK INC)<br>8 June 1995 (1995-06-08)   | 1,2,5-7,<br>12-15      |
| Y          | page 3, line 24 - line 31; figures 1-9   | 3,4,<br>8-11,16,<br>28 |
| Y          | EP 0 646 366 A (ACROMED CORP)<br>5 April 1995 (1995-04-05)<br>column 3, line 42 -column 4, line 38;<br>figures | 3,4,8,16               |
| Y          | WO 95 08964 A (BRANTIGAN JOHN W)<br>6 April 1995 (1995-04-06)<br>the whole document                            | 9-11                   |
|            | -/-  |                        |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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# INTERNATIONAL SEARCH REPORT

national Application No  
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Information on patent family members

I. International Application No

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| (21) Internationales Aktenzeichen: PCT/CH98/00441<br>(22) Internationales Anmeldedatum: 15. Oktober 1998 (15.10.98)<br><br>(71) Anmelder (für alle Bestimmungsstaaten ausser CA US): SYNTHES AG CHUR [CH/CH]; Grabenstrasse 8, CH-8008 Zürich (CH).<br><br>(71) Anmelder (nur für CA): SYNTHES (U.S.A.) [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).<br><br>(72) Erfinder; und<br>(75) Erfinder/Anmelder (nur für US): LÄNG, Bruno [CH/CH]; Rainstrasse 256, CH-4557 Horriwil (CH). BENOIT, Alfred [CH/CH]; Nelkenweg 7, CH-2543 Lengnau (CH).<br><br>(74) Anwalt: LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH). |    | (81) Bestimmungsstaaten: AU, CA, JP, US, europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).<br><br>Veröffentlicht<br>Mit internationalem Recherchenbericht. |

(54) Title: TELESCOPIC VERTEBRAL PROSTHESIS

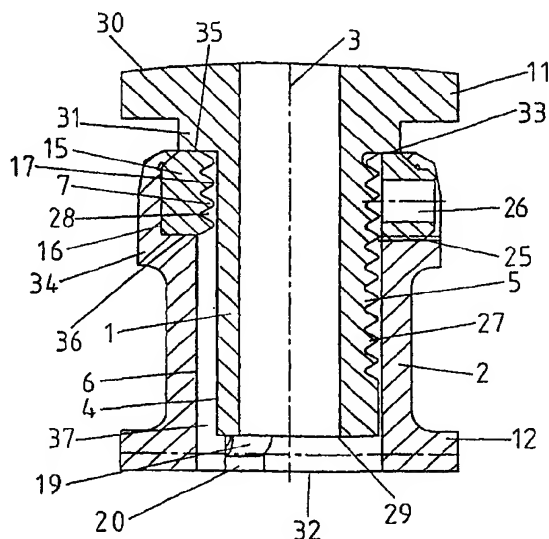
(54) Bezeichnung: TELESKOPIERENDE WIRBELPROTHESE

## (57) Abstract

The invention relates to a device for replacing vertebral bones in the human body, comprising one inner (1) and one outer (2) longitudinal hollow body. These hollow bodies (1, 2) can coaxially slide into each other along a central axis (3) and can be displaced in relation to one another in the direction of said central axis (3). The inner hollow body (1) is provided with first coupling elements (5) on its outer surface (4) and second coupling elements (7), which can be engaged with the first coupling elements (5), are arranged in the cavity (37) of the outer hollow body (2). The first and second coupling elements (5, 7) are positioned on the outer surface (4) and in the cavity (37) in such a way that they can optionally adopt at least two different positions by twisting in relation to each other; a first position (A), in which they are engaged with each other in such a way that the two hollow bodies (1, 2) are blocked in relation to each other in the direction of the central axis (3); and a second position (B), in which they are not engaged with each other so that the two hollow bodies (1, 2) can move relatively freely in relation to each other in the direction of the central axis (3).

## (57) Zusammenfassung

Vorrichtung zum Ersatz von Wirbelkörpern im menschlichen Körper, die einen inneren (1) und einen äusseren (2) longitudinalen Hohlkörper umfasst, welche entlang einer Zentralachse (3) ineinander gleitbar und in Richtung dieser Zentralachse (3) relativ zueinander verschiebbar sind und der innere Hohlkörper (1) an seiner äusseren Mantelfläche (4) mit ersten Kupplungselementen (5) versehen ist, während im Hohlraum (37) des äusseren Hohlkörpers (2) zweite Kupplungselemente (7) angebracht sind, welche mit den ersten Kupplungselementen (5) in Eingriff bringbar sind. Diese ersten und zweiten Kupplungselemente (5; 7) sind an der Mantelflächen (4) und im Hohlraum (37) derart angeordnet, dass sie durch relative Verdrehung zueinander wahlweise in mindestens zwei verschiedene Positionen bringbar sind, einer ersten Position (A), in welcher die ersten und zweiten Kupplungselemente (5; 7) miteinander im Eingriff stehen, so dass die beiden Hohlkörper (1; 2) in Richtung der Zentralachse (3) relativ zueinander blockiert sind; und einer zweiten Position (B), in welcher die ersten und zweiten Kupplungselemente (5; 7) nicht miteinander im Eingriff stehen, so dass die beiden Hohlkörper (1; 2) in Richtung der Zentralachse (3) relativ zueinander frei beweglich sind.



### LEDIGLICH ZUR INFORMATION

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### Teleskopierende Wirbelprothese

Die Erfindung bezieht sich auf eine Vorrichtung zum Ersatz von Wirbelkörpern der menschlichen Wirbelsäule gemäss dem Oberbegriff des Patentanspruchs 1.

Wird ein Wirbelkörper krank oder erleidet er einen Defekt, so muss dieser aus der Wirbelsäule entfernt werden. Aus dem Stand der Technik sind einige distanzhaltende Implantate zum Ersatz des fehlenden Wirbelkörpers bekannt. Solche Implantate umfassen üblicherweise gegeneinander verschiebbare Teile, die unter anderem mittels Verzahnungen eine Einstellung der Länge des Implantates gestatten, und zwei spezielle Endplatten, die zur Verankerung des Implantates in den anschliessenden intakten Wirbelkörpern dienen.

Aus der US 4,554,914 KAPP ET AL. ist beispielsweise eine Wirbelkörperprothese bekannt, welche nach dem Entfernen eines defekten Wirbelkörpers zwischen die beiden an diesen angrenzenden gesunden Wirbelkörper eingesetzt wird. Diese bekannte Wirbelkörperprothese umfasst ein Paar längenverstellbarer Stützelemente und Befestigungsmittel. Diese längenverstellbaren Stützelemente werden in den durch die Entfernung eines defekten

Wirbelkörpers entstehenden Hohlraum zwischen den benachbarten gesunden Wirbelkörpern eingefügt. Dazu wird nach dem Herstellen des Hohlraumes eine Spreizvorrichtung zwischen die einander gegenüberliegenden Wirbelkörperflächen der benachbarten Wirbelkörper eingesetzt, mittels welcher diese Wirbelkörper distrahiert werden und die normale Höhe des zu ersetzenden Wirbelkörpers wieder hergestellt wird. Die Stützelemente stützen die angrenzenden Wirbelkörper axial und justieren den axialen Zwischenraum zwischen den benachbarten Wirbelkörpern. Zusätzlich wird um die längenverstellbaren Stützelemente ein fließfähiges und aushärtendes Material eingefügt, so dass die Stützelemente darin eingebettet werden. Die Stützelemente bestehen aus einer Hülse mit einer Bohrung mit Innengewinde und darin einschraubbaren Schrauben. Zudem umfassen die Hülsen am äusseren Ende konische Spitzen während die Schrauben am ihrem äusseren Ende keilförmig gestaltet sind. Durch Expansion der Stützelemente im Hohlraum zwischen den Wirbelkörpern wird erreicht, dass die äusseren Ende von Hülsen und Schrauben in die benachbarten Wirbelkörper eindringen. Die konischen Spitzen gestatten, dass die Hülse drehbar ist, während die keilförmigen äusseren Enden der Schrauben eine Drehung der Schrauben verhindern, so dass die Einstellung der Länge des Stützelementes durch Drehen der Hülse erfolgen kann. Die Befestigungsmittel bestehen aus je zwei länglichen Platten mit Vertiefungen und Schraubenlöchern. Diese Platten werden beidseits der Wirbelsäule an die dorsalen Fortsätze der Wirbelkörper angelegt und verschraubt. Die Schraubenlöcher in den Platten sind so angeordnet, dass die Schrauben die dorsalen Fortsätze der

Wirbelkörper durchdringen und somit die Wirbelsäule im Bereich der Wirbelprothese fixieren.

Der Nachteil dieser bekannten Wirbelprothese besteht darin, dass die Stützelemente lediglich bei exakt axialer Belastung eine genügende Stabilität bieten. Ferner ist das Einbringen zweier solcher Stützelemente in den Hohlraum zwischen den angrenzenden gesunden Wirbelkörpern und deren Längenausrichtung mittels der Gewinde zeitraubend.

Der Erfindung liegt die Aufgabe zugrunde, eine stabile, längeneinstellbare und intraoperativ einfach handbare Wirbelprothese zu schaffen, welche die biomechanischen und physiologischen Eigenschaften der Wirbelsäule trotz des entfernten Wirbelkörpers aufrecht erhält.

Die Erfindung löst die gestellte Aufgabe mit einer Vorrichtung, welche die Merkmale des Anspruchs 1 aufweist.

In einer bevorzugten Ausführungsform der erfindungsgemässen Vorrichtung umfasst diese zwei Hohlzylinder, welche entlang einer Zentralachse ineinander verschiebbar und teleskopierbar sind, und einen hohlzylindrischen, konzentrisch zur Zentralachse der beiden Hohlzylinder angeordneten Fixierring, welcher in einer innerhalb der inneren Mantelfläche des äusseren Hohlzylinders angebrachten Nute um die Zentralachse drehbar gelagert ist. An der äusseren Mantelfläche des inneren

Hohlzylinders sind sektoriell Erhebungen angebracht, welche die Form eines Gewindes ohne Steigung aufweisen. Zu diesen Erhebungen korrespondierend sind an der Oberfläche der Bohrung im Fixierring ebenfalls sektoriell Vertiefungen angebracht, so dass beim Eingriff der Erhebungen in die Vertiefungen eine axiale Blockierung der beiden Hohlzylinder gegeneinander hergestellt wird. Die drei Sektoren mit Vertiefungen am Fixierring und diejenigen drei Sektoren mit Erhebungen am inneren Hohlzylinder weisen jeweils einen Sektorwinkel von  $60^\circ$  auf. Alternierend zwischen diesen mit Erhebungen beziehungsweise Vertiefungen versehenen Sektoren liegen Sektoren mit einem Sektorwinkel von ebenfalls  $60^\circ$ , worin am inneren Hohlzylinder keine Erhebungen und am Fixierring keine Vertiefungen angebracht sind und deren Durchmesser so gestaltet sind, dass eine axiale Verschiebung des inneren und des äusseren Hohlzylinders gegeneinander möglich ist. Damit ist gewährleistet, dass in einer ersten Drehwinkelstellung (Position A) des Fixierringes Erhebungen und Vertiefungen miteinander in Eingriff stehen und somit die beiden Hohlkörper in Richtung der Zentralachse relativ zueinander blockiert sind während in einer zweiten Drehwinkelstellung (Position B) des Fixierringes die Erhebungen und Vertiefungen nicht miteinander im Eingriff stehen, so dass die beiden Hohlkörper in Richtung der Zentralachse relativ zueinander frei beweglich sind.

An den freien Enden des inneren und des äusseren Hohlzylinders sind Endplatten angebracht, welche einen grösseren Durchmesser als der innere beziehungsweise der äussere Hohlzylinder

aufweisen. Diese Endplatten sind an den zur Anlage an die benachbarten Wirbelknochen bestimmten freien Flächen mit einer dreidimensionalen Strukturierung versehen, welche aus konischen oder pyramidenförmigen Spitzen besteht. Bei der Implantation der Vorrichtung wird diese gespreizt, wobei sich diese Spitzen in die Oberflächen der benachbarten Wirbelkörper eingraben und somit das Implantat gegen Verrutschen innerhalb des ausgeräumten Wirbelraumes sichern.

Beide Hohlzylinder sind entlang der Zentralachse durchgehend durchbohrt. Der dadurch erreichte Hohlraum kann mit Knochenspänen aufgefüllt werden, wodurch das Zusammenwachsen der beiden benachbarten Wirbelkörper im Hohlraum der Vorrichtung gefördert wird. Zur Förderung des Anwachsens der benachbarten Wirbelkörper am Implantat können die an diese Wirbelkörper angrenzenden Endplatten der Vorrichtung perforiert sein.

Zur Sicherung gegen Verdrehen der beiden Hohlzylinder ist an der inneren Mantelfläche des äusseren Hohlzylinders eine entlang der Zentralachse verlaufende Nut und am inneren Hohlzylinder eine in diese Nut eingreifende Nase angebracht. Damit wird verhindert, dass beim Drehen des Fixierringes von einer Position zur Anderen die Hohlzylinder gegeneinander verdreht werden.

An der äusseren Mantelfläche des Fixierringes ist ein Ansatz angebracht, welcher in einer entsprechenden Aussparung am äusseren Hohlzylinder so bewegbar ist, dass eine Drehbewegung

des Fixierringes zwischen den Positionen A) und B) möglich ist und die Nase des Fixierringes in der Position A) an der einen Seitenwand der Aussparung und in der Position B) an der anderen Seitenwand der Aussparung anschlägt. Diese so erreichten seitlichen Anschläge für den Ansatz am Fixierring gestatten ein einfaches Auffinden des ersten Drehwinkels des Fixierringes, bei dem die beiden Hohlzylinder axial fest sind, und des zweiten Drehwinkels des Fixierringes, bei dem die beiden Hohlzylinder axial verschiebbar sind. Zur Sicherung des Fixierringes in einer gewählten Position ist am Ansatz eine in axialer Richtung vorstehende v-förmige Erhebung angebracht, welche in entsprechende Rillen in der Aussparung einrastet, so dass der Fixierring in den Positionen A) und B) lösbar fixierbar ist.

Die durch die Erfindung erreichten Vorteile sind im wesentlichen darin zu sehen, dass dank der erfindungsgemässen Vorrichtung bei axialer Belastung eine hohe Stabilität erreicht wird und die benachbarten Wirbelkörper auf einem ausreichend grossen Querschnitt zusammenwachsen können. Beim Einbringen der Vorrichtung in den ausgeräumten Wirbelraum wird die Vorrichtung mittels einer Spreizzange solange verlängert, bis die Endplatten an den Hohlzylindern an die angrenzenden gesunden Wirbelkörper anstossen und die Spitzen genügend weit in diese Wirbelkörper eindringen. Dazu wird vorangehend der Fixierring in seine zweite Drehwinkelstellung (Position B) gebracht. Nach Erreichen der erforderlichen Länge des Implantates wird der Fixierring mittels eines Stabes, welcher in eine speziell dazu vorgesehene Bohrung im Fixierring einbringbar ist, in seine erste Drehwinkelstellung



(Position A) gebracht und somit die Vorrichtung auf der gewünschten Länge blockiert. Diese Längenblockierung des Implantates gewährleistet eine einfache Handhabung bei der Implantation der Vorrichtung.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1 einen Längsschnitt durch die bevorzugte Ausführungsform der erfindungsgemässen Vorrichtung in ihrer minimalen Höhe mit nicht im Eingriff stehenden Kupplungselementen;

Fig. 2 einen Querschnitt durch die in Fig. 1 dargestellte Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 3 einen Längsschnitt durch die bevorzugte Ausführungsform der erfindungsgemässen Vorrichtung mit vergrößerter Höhe und im Eingriff stehenden Kupplungselementen; und

Fig. 4 einen Querschnitt durch die in Fig. 3 dargestellte Ausführungsform der erfindungsgemässen Vorrichtung.

Fig. 1 zeigt die bevorzugte Ausführungsform der erfindungsgemässen Vorrichtung in einem Längsschnitt. Die Vorrichtung umfasst einen inneren Hohlkörper 1, einen äusseren Hohlkörper 2 und

einen Fixierring 15. Der innere 1 und der äussere Hohlkörper 2 sind konzentrisch zu einer Zentralachse 3 so angeordnet, dass der innere Hohlkörper 1 im ebenfalls konzentrisch verlaufenden Hohlraum 37 des äusseren Hohlkörpers 2 entlang der Zentralachse 3 verschiebbar ist. Dadurch entsteht eine teleskopierbare Anordnung der beiden Hohlkörper 1;2. In der in Fig. 1 gezeigten Anordnung der Vorrichtung ist der innere Hohlkörper 1 so weit wie möglich in den Hohlraum des äusseren Hohlkörpers 2 eingefahren, wodurch die so dargestellte Vorrichtung ihre geringste mögliche Höhe einnimmt. Der innere Hohlkörper 1 besteht an seinem oberen Ende 30 aus einer polygonförmigen Endplatte 11, einer daran anschliessenden kreiszyklindrischen Andrehung 31 und einem zylindrischen Teil mit der äusseren Mantelfläche 4, wobei diese äussere Mantelfläche 4 mit Erhebungen 27 versehen ist, welche als erste Kupplungselemente 5 dienen. Diese Erhebungen 27 sind auf der äusseren Mantelfläche 4 in Sektoren 8 mit einem Winkel von  $60^\circ$  angeordnet, wobei zwischen diesen mit Erhebungen 27 versehenen Sektoren 8 alternierend Sektoren 10 ohne Erhebungen 27 liegen. Die Sektoren 10 schliessen ebenfalls einen Winkel von  $60^\circ$  ein. Die Erhebungen 27 weisen die Form und das Profil eines Gewindes ohne Steigung auf. Der äussere Hohlkörper 2 besteht aus einer weiteren polygonförmigen Endplatte 12 an seinem unteren Ende 32, einem daran anschliessenden kreiszyklindrischen Mittelteil und einem ebenfalls kreiszyklindrischen, einen grösseren Durchmesser als das Mittelteil aufweisenden Oberteil gegen das obere Ende 33. Der konzentrisch zur Zentralachse 3 verlaufende kreiszyklindrische Hohlraum 37 des äusseren Hohlkörpers 2 ist in seinem

Durchmesser so bemessen, dass der innere Hohlkörper 1 mit seinem mit den ersten Kupplungselementen 5 versehenen Teil in Richtung der Zentralachse 3 innerhalb dieses Hohlraumes 37 verschiebbar ist. Zudem ist in der Mantelfläche 6 des Hohlraumes 37 des äusseren Hohlkörpers 2 parallel zur Zentralachse 3 eine Nut 20 angebracht, deren Abmessungen so gestaltet sind, dass eine am unteren Ende 29 des inneren Hohlkörpers 1 angebrachte Nase 19 in diese Nut 20 eingreifen kann, womit sich eine Verdrehung der beiden Hohlkörper 1;2 relativ zueinander verhindern lässt. Die axiale Länge der Nut 20 ist so bemessen, dass der innere Hohlkörper 1 auf seiner mit den ersten Kupplungselementen 5 versehenen Länge teleskopierbar ist. Zur Fixierung der axialen Position des inneren Hohlkörpers 1 gegenüber dem äusseren Hohlzylinder 2 ist in eine an der inneren Mantelfläche 6 des äusseren Hohlzylinders 2 konzentrisch zur Zentralachse 3 angebrachten umlaufenden Nut 16 ein Fixierring 15 mit zweiten Kupplungselementen 7 um die Zentralachse 3 drehbar eingefügt. Der Fixierring 15 hat die Form eines zylindrischen Ringes, dessen innere Mantelfläche 17 mit Vertiefungen 28 versehen ist, welche als zweite Kupplungselemente 7 dienen. Diese Vertiefungen 28 sind auf der inneren Mantelfläche 17 in Sektoren 10 mit einem Winkel von  $60^\circ$  angeordnet, wobei zwischen diesen mit Vertiefungen 28 versehenen Sektoren 10 alternierend Sektoren 9 ohne Vertiefungen 28 liegen. Die Sektoren 9 schliessen ebenfalls einen Winkel von  $60^\circ$  ein. Die Vertiefungen 28 weisen die Form und das Profil eines zu den Erhebungen 27 an der äusseren Mantelfläche 4 des inneren Hohlkörpers 1 korrespondierenden Gewindes ohne Steigung auf. In Fig. 1 und 2 sind die am inneren

Hohlkörper 1 angebrachten ersten Kupplungselemente 5 und die am Fixierring 15 angebrachten zweiten Kupplungselemente 7 in der Position B) dargestellt. Das heisst, die Kupplungselemente 5;7 stehen miteinander nicht im Eingriff und die beiden Hohlkörper 1;2 sind in Richtung der Zentralachse 3 relativ zueinander frei beweglich. Zum einfacheren Einstellen der Positionen A) und B) ist der Fixierring 15 mit einem Ansatz 22 versehen, welche in eine am äusseren Hohlzylinder 2 angebrachte Aussparung 21 eingreift, wobei diese Aussparung 21 so bemessen ist, dass sie eine Drehbewegung des Fixierringes 15 zwischen den Positionen A) und B) zulässt. Zudem ist am Ansatz 22 eine in axialer Richtung vorstehende v-förmige Erhebung 25 angebracht, welcher in entsprechende Rillen 23;24 in der Aussparung 21 einrastet, so dass der Fixierring 15 in den Positionen A) und B) lösbar fixierbar ist. Ebenfalls am Ansatz 22 angebracht ist eine radiale Bohrung 26. Zur Drehung des Fixierringes 15 von der einen Position A);B) in die jeweils andere Position A);B) kann ein gewöhnlicher Dorn (nicht gezeichnet) in die Bohrung 26 eingeführt werden und als Hebelarm benützt werden.

In Fig. 3 ist die erfindungsgemässe Vorrichtung in einer verlängerten und blockierten Position dargestellt. Wie in Fig. 4 gezeigt, nimmt dazu der Fixierring die Position A) ein, das heisst, die Kupplungselemente 5;7 sind im Eingriff. In dieser Position A) bilden die Vertiefungen 28 mit den Erhebungen 27 eine formschlüssige Verbindung, welche eine Verschiebung der beiden Hohlkörper 1;2 gegeneinander in Richtung der Zentralachse 3 verhindert. Die in Fig. 3 dargestellte Ausführungsform der

erfindungsgemässen Vorrichtung unterscheidet sich sonst von der in Fig. 1 dargestellten Ausführungsform nur dadurch, dass an den freien Endflächen am unteren Ende 32 der äusseren Hohlzylinders 2 und am oberen Ende 30 des inneren Hohlzylinders 1 konische Spitzen 13 angebracht sind, welche in die jeweils angrenzenden gesunden Wirbelkörper eindringen können. Ebenfalls sind beide Endplatten 11;12 perforiert, wodurch ein Anwachsen der angrenzenden Wirbelkörper an die implantierte Vorrichtung gefördert wird.

Patentansprüche

1. Vorrichtung zum Ersatz von Wirbelkörpern im menschlichen Körper, die einen inneren (1) und einen äusseren (2) longitudinalen Hohlkörper umfasst, welche entlang einer Zentralachse (3) ineinander koaxial gleitbar und in Richtung dieser Zentralachse (3) relativ zueinander verschiebbar sind und der innere Hohlkörper (1) an seiner äusseren Mantelfläche (4) mit ersten Kupplungselementen (5) versehen ist, während im Hohlraum (37) des äusseren Hohlkörpers (2) zweite Kupplungselemente (7) angeordnet sind, welche mit den ersten Kupplungselementen (5) in Eingriff bringbar sind,

**dadurch gekennzeichnet, dass**

die ersten und zweiten Kupplungselemente (5;7) derart zueinander angeordnet sind, dass sie durch relative Verdrehung zueinander wahlweise in mindestens zwei verschiedene Positionen bringbar sind,

einer ersten Position (A), in welcher die ersten und zweiten Kupplungselemente (5;7) miteinander im Eingriff stehen, so dass die beiden Hohlkörper (1;2) in Richtung der Zentralachse (3) relativ zueinander blockiert sind; und

einer zweiten Position (B) in welcher die ersten und zweiten Kupplungselemente (5;7) nicht miteinander im Eingriff stehen, so dass die beiden Hohlkörper (1;2) in Richtung der Zentralachse (3) relativ zueinander frei beweglich sind.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die ersten Kupplungselemente (5) aus Erhebungen auf der äusseren Mantelfläche (4) und die zweiten Kupplungselemente (7) aus Vertiefungen in der inneren Mantelfläche (6) des äusseren Hohlkörpers (2) bestehen, welche mit den Erhebungen korrespondieren.

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, dass die ersten Kupplungselemente (5) auf einen oder mehrere Sektoren (8) der äusseren Mantelfläche (4) beschränkt sind und die zweiten Kupplungselemente (7) auf einen oder mehrere Sektoren (10) der inneren Mantelfläche (6) beschränkt sind, wobei die Sektoren (8;10) auf den beiden Mantelflächen (4;6) den gleichen Winkel aufweisen.

4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass die Sektoren (8;10), innerhalb welcher die Kupplungselemente (5;7) angebracht sind, mit Sektoren (9;18) ohne Kupplungselemente (5;7) alternierend angeordnet sind.

5. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass der äussere Hohlkörper (2) zusätzlich einen hohlzylindrischen, konzentrisch zur Zentralachse (3) angeordneten Fixierring (15) umfasst, welcher in einer innerhalb der inneren Mantelfläche (6) angebrachten Nute (16) drehbar gelagert ist, und die zweiten Kupplungselemente (7) an der Manteloberfläche der Bohrung (17) des Fixierringes (15) angebracht sind.

6. Vorrichtung nach Anspruch 5, dadurch gekennzeichnet, dass die ersten Kupplungselemente (5) aus Erhebungen auf der äusseren Mantelfläche (4) und die zweiten Kupplungselemente (7) aus Vertiefungen in der Manteloberfläche der Bohrung (17) bestehen, welche mit den Erhebungen korrespondieren.

7. Vorrichtung nach Anspruch 5 oder 6, dadurch gekennzeichnet, dass die ersten Kupplungselemente (5) auf einen oder mehrere Sektoren (8) der äusseren Mantelfläche (4) beschränkt sind und die zweiten Kupplungselemente (7) auf einen oder mehrere Sektoren (10) der Bohrung (17) beschränkt sind, wobei die Sektoren (8) auf der äusseren Mantelfläche (4) und die Sektoren (10) auf der Manteloberfläche der Bohrung (17) den gleichen Winkel aufweisen.

8. Vorrichtung nach Anspruch 7, dadurch gekennzeichnet, dass die Sektoren (8;10), innerhalb welcher die Kupplungselemente (5;7) angebracht sind, mit Sektoren (9;18) ohne Kupplungselemente (5;7) alternierend angeordnet sind.

9. Vorrichtung nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass beide Hohlkörper (1;2) hohlzylindrisch sind.

10. Vorrichtung nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass die beiden Hohlkörper (1;2) einen nicht kreisförmigen Querschnitt haben.



11. Vorrichtung nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass am freien Ende des inneren Hohlkörpers (1) eine Endplatte (11) angebracht ist.

12. Vorrichtung nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass am freien Ende des äusseren Hohlkörpers (2) eine Endplatte (12) angebracht ist.

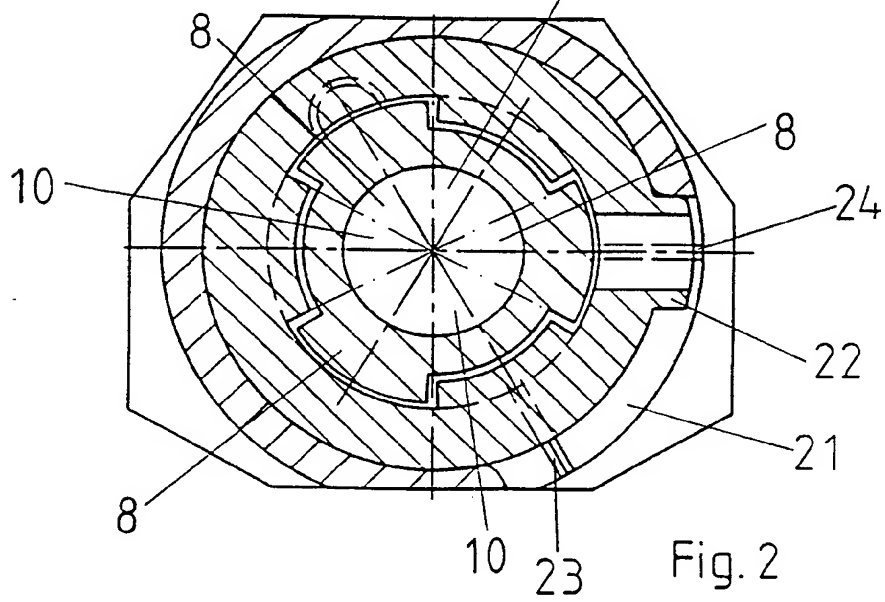
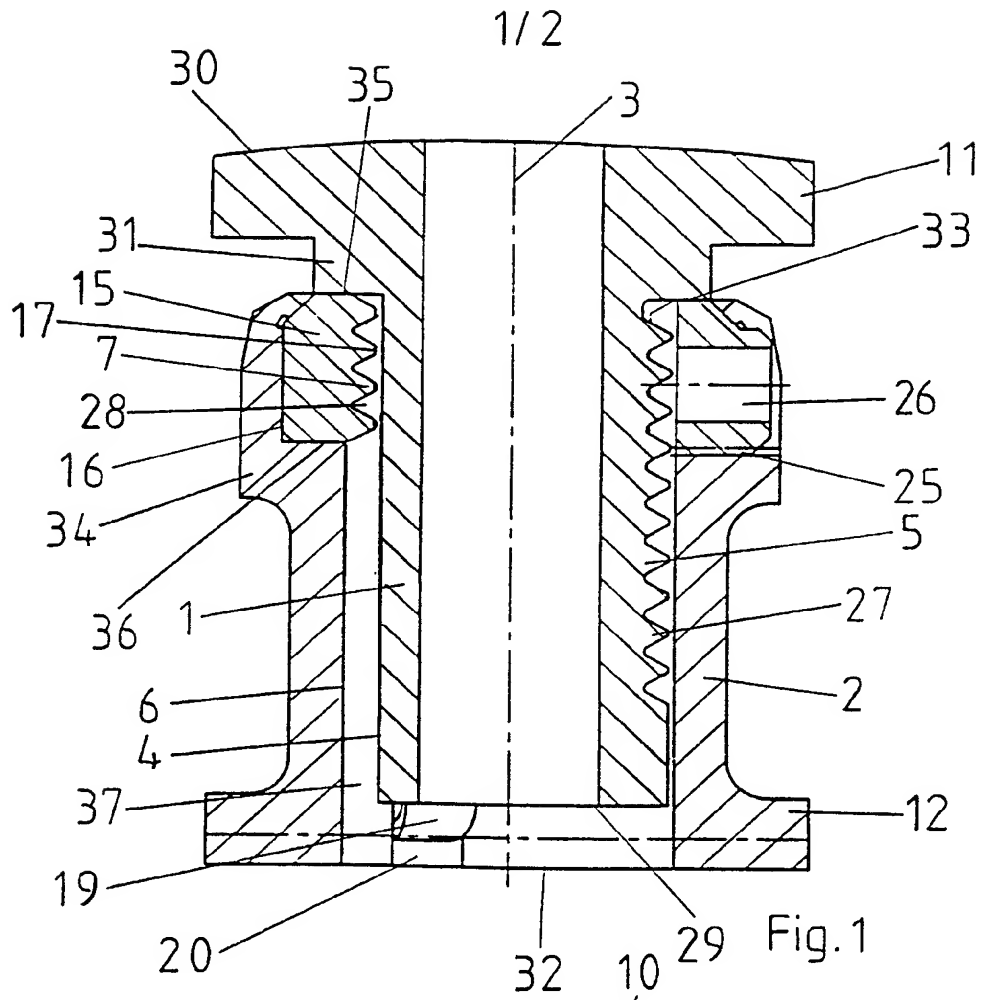
13. Vorrichtung nach einem der Ansprüche 11 oder 12, dadurch gekennzeichnet, dass die zur Anlage am Wirbelknochen bestimmte freie Fläche der Endplatte (11;12) eine dreidimensionale Strukturierung (13) aufweist.

14. Vorrichtung nach einem der Ansprüche 11 oder 12, dadurch gekennzeichnet, dass die zur Anlage am Wirbelknochen bestimmte freie Fläche der Endplatte (11;12) Perforierungen (14) aufweist.

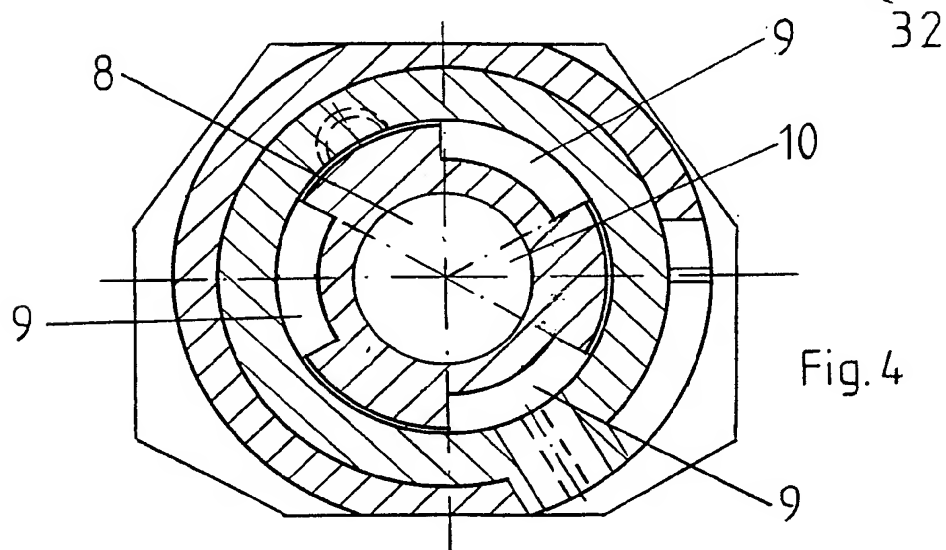
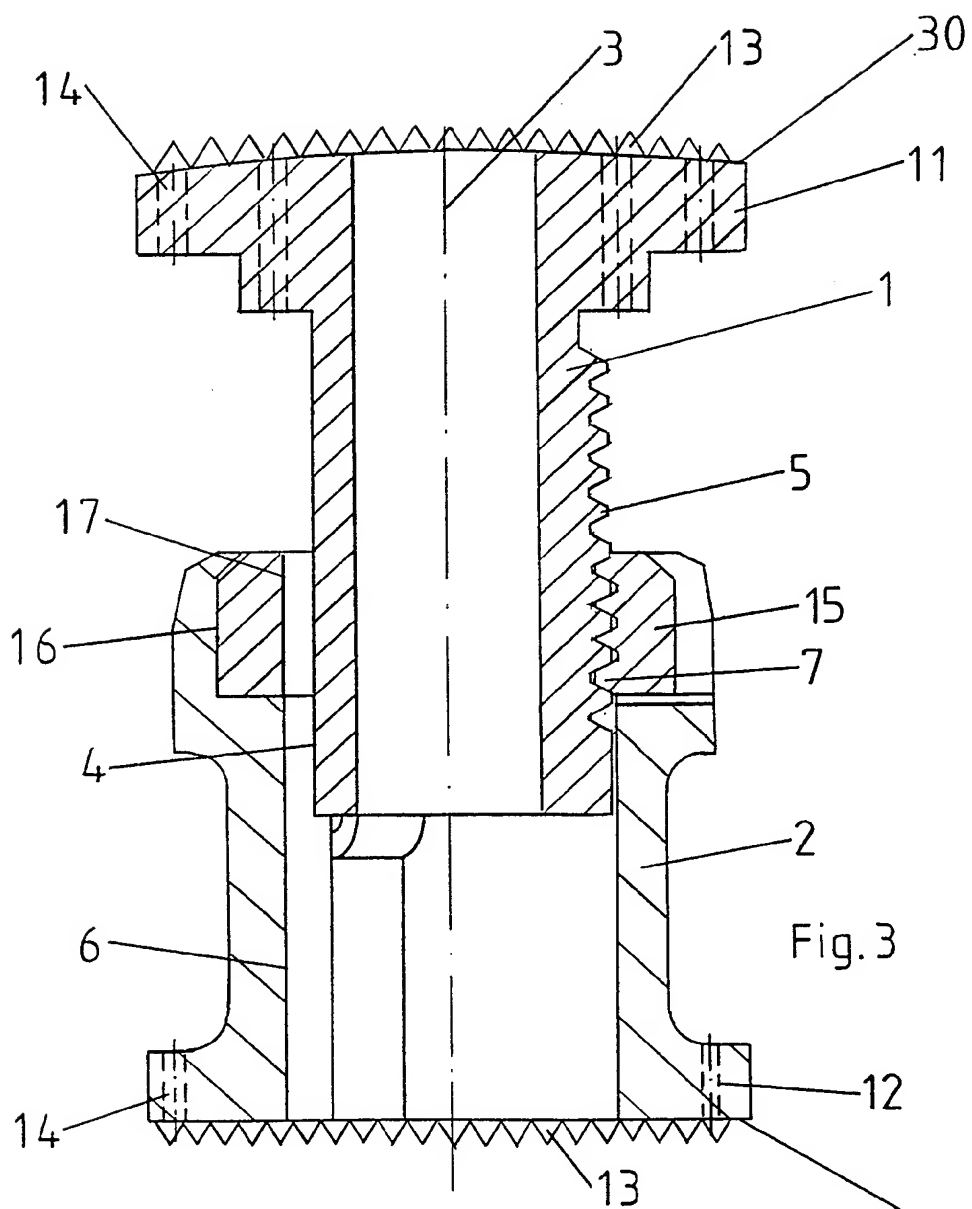
15. Vorrichtung nach einem der Ansprüche 5 bis 14, dadurch gekennzeichnet, dass der äussere Hohlzylinder (2) an seiner inneren Mantelfläche (6) mit einer entlang der Zentralachse (3) verlaufenden Nut (20) versehen ist und der innere Hohlzylinder (1) eine darin eingreifende Nase (19) aufweist, so dass sich die beiden Hohlzylinder (1;2) nicht gegeneinander verdrehen können.

16. Vorrichtung nach einem der Ansprüche 5 bis 15, dadurch gekennzeichnet, dass der Fixierring (15) mit einem Ansatz (22) versehen ist, welcher in eine am äusseren Hohlzylinder (2) angebrachte Aussparung (21) eingreift, wobei diese Aussparung (21) so bemessen ist, dass sie eine Drehbewegung des Fixierringes (15) zwischen den Positionen A) und B) zulässt.

17. Vorrichtung nach Anspruch 16, dadurch gekennzeichnet, dass am Ansatz (22) eine in axialer Richtung vorstehende v-förmige Erhebung (25) angebracht ist, welche in entsprechende Rillen (23;24) einrastet, so dass der Fixierring (15) in den Positionen A) und B) lösbar fixierbar ist.



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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/CH 98/00441

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages           | Relevant to claim No. |
|------------|--|-----------------------|
| X          | DE 30 23 942 A (WALDEMAR LINK GMBH & CO)<br>14 January 1982<br>see page 6; figures 1-5       | 1-4, 9-12             |
| Y          | ----   | 13-15                 |
| Y          | DE 196 22 827 A (ULRICH HEINRICH)<br>11 December 1997<br>see claim 3; figure 2               | 13, 15                |
| Y          | ----   |                       |
| Y          | WO 96 17564 A (SOFAMOR DANKE GROUP INC)<br>13 June 1996<br>see figures 3, 4                  | 14                    |
| A          | ----   | 13                    |
| A          | DE 27 50 648 A (MECRON MED PROD GMBH)<br>17 May 1979<br>see page 7, paragraph 3; figures 1-5 | 5-8                   |
|            | ----   |                       |
|            | -/--   |                       |

☒ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

8 June 1999

Date of mailing of the international search report

15/06/1999

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# INTERNATIONAL SEARCH REPORT

Inter.      nal Application No

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages            | Relevant to claim No. |
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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CH 98/00441

| Patent document<br>cited in search report |   | Publication<br>date | Patent family<br>member(s)  | Publication<br>date  |
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# INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/CH 98/00441

## A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES

IPK 6 A61F2/44

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

## B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)

IPK 6 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

## C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

| Kategorie* | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile | Betr. Anspruch Nr. |
|------------|--|--------------------|
| X          | DE 30 23 942 A (WALDEMAR LINK GMBH & CO)<br>14. Januar 1982<br>siehe Seite 6; Abbildungen 1-5      | 1-4, 9-12          |
| Y          | ---  | 13-15              |
| Y          | DE 196 22 827 A (ULRICH HEINRICH)<br>11. Dezember 1997<br>siehe Anspruch 3; Abbildung 2            | 13, 15             |
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|            | ---  |                    |
|            | -/--   |                    |

☒ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

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Datum des Abschlusses der internationalen Recherche

8. Juni 1999

Absenddatum des internationalen Recherchenberichts

15/06/1999

Name und Postanschrift der Internationalen Recherchenbehörde  
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Bevollmächtigter Bediensteter

Stach, R



# INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/CH 98/00441

## C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

| Kategorie <sup>a</sup> | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile | Betr. Anspruch Nr. |
|------------------------|--|--------------------|
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Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen

PCT/CH 98/00441

| Im Recherchenbericht<br>angeführtes Patentdokument |   | Datum der<br>Veröffentlichung | Mitglied(er) der<br>Patentfamilie |            | Datum der<br>Veröffentlichung |
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